TABLE 1. Comparison of HRQoL scores of gouty arthritis patients treated with canakinumab and triamcinolone acetonide

Component	General US population[a]	Canakinumab 150 mg s.c.			Triamcinolone acetonide 40 mg i.m.		
		Baseline N = 27	7 days post-dose N = 26†		Baseline N = 56	7 days post-dose N = 54†	
		Score	Score	Change from baseline	Score	Score	Change from baseline
SF-36® scores (0-100)							
Physical Component Summary Score (PCS)	50.0# (10.0)	36.4 (8.2)	48.3 (8.6)	12.0 (10.0)	33.5 (9.2)	41.9 (9.4)	8.5 (10.4)
Mental Component Summary Score (MCS)	50.0# (10.0)	46.7 (13.6)	50.7 (11.2)*	3.4 (11.0)	44.7 (15.1)	47.9 (12.4)	2.9 (13.5)
SF-36® subscale scores							
Physical functioning	84.2 (23.3)	41.5 (30.2)	80.0 (25.5)	39.0 (30.9)	38.4 (26.5)	61.5 (29.3)	23.3 (34.6)
Role-physical	80.9 (34.0)	53.0 (32.5)	71.2 (26.8)	18.3 (28.7)	43.2 (25.4)	60.5 (29.0)	17.4 (32.4)
Bodily Pain	75.2 (23.7)	36.0 (26.6)	72.2 (22.0)	35.6 (38.8)	32.4 (25.7)	53.7 (28.6)	21.3 (35.3)
General health	71.9 (20.3)	65.4 (18.0)	71.2 (18.5)	4.6 (8.6)	56.0 (20.2)	61.8 (20.7)	5.5 (18.3)
Vitality	60.9 (20.9)	53.9 (20.5)	66.6 (18.5)*	12.3 (19.5)	48.9 (25.3)	58.6 (25.5)	9.8 (24.7)
Social functioning	83.3 (22.7)	61.6 (32.1)	81.7 (23.5)	18.8 (28.3)	52.5 (29.9)	70.1 (28.3)	17.1 (32.5)
Role-emotional	81.3 (33.0)	63.9 (32.6)	80.8 (25.0)	16.3 (32.1)	66.5 (31.5)	72.1 (27.4)	6.2 (33.3)
Mental health	74.7 (18.1)	67.4 (21.1)	78.1 (18.2)*	9.6 (14.4)	60.5 (25.1)	68.5 (22.8)	8.5 (23.3)
HAQ-DI (0-3)	NA	0.8 (0.7)	0.3 (0.4)	-0.5 (0.7)	1.1 (0.7)	0.6 (0.6)	−0.5 (0.5)

Mean (S.D.) values are presented throughout; †some scores evaluations were missing for up to 3 patients of the group; #normalized scores representing an average US person with no chronic disease; *reached general population levels; NA: not available. Reference: a Adapted from Ware J et al. SF-36® Physical and Mental Health Summary Scales: A User's Manual, Boston, MA: The Health Institute. 1994

Metabolic and crystal arthropathies

112. RAPID IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE IN GOUTY ARTHRITIS PATIENTS TREATED WITH CANAKINUMAB (ACZ885) COMPARED TO TRIAMCINOLONE ACETONIDE

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Background: Canakinumab, a fully human anti-IL-1β antibody has been shown to control inflammation in gouty arthritis. This study evaluated changes in health-related quality of life (HRQoL) in patients treated with canakinumab or triamcinolone acetonide (TA).
Methods: An 8-wk, dose-ranging, active controlled, single-blind study in patients (≥18 to ≤80 years) with acute gouty arthritis flare, refractory to or contraindicated to NSAIDs and/or colchicine, were randomized to canakinumab 10, 25, 50, 90, 150 mg sc or TA 40 mg im. HRQoL was assessed using patient reported outcomes evaluating PCS and MCS, and subscale scores of SF-36® [acute version 2]) and functional disability (HAQ-DI©).
Results: In canakinumab 150 mg group, the most severe impairment at baseline was reported for physical functioning and bodily pain; levels of 41.5 and 36.0, respectively, which improved in 7 days to 80.0 and 72.2 (mean increases of 39.0 and 35.6) and at 8 wks improved to 86.1 and 86.6 (mean increases of 44.6 and 50.6); these were higher than levels seen in the general US population. TA group, showed less improvement in 7 days (mean increases of 23.3 and 21.3 for physical function and bodily pain). Functional disability scores, measured by the HAQ-DI© decreased in both treatment groups (Table 1).
Conclusions: Gouty arthritis patients treated with canakinumab showed a rapid improvement in physical and mental well-being based on SF-36® scores. In contrast to the TA group, patients treated with canakinumab showed improvement in 7 days in physical function and bodily pain approaching levels of the general population.
Disclosure statement: U.A., A.F., V.M., D.R., P.S. and K.S. are employees and shareholders of Novartis Pharma AG. A.P. has received research support from Novartis Pharma AG. N.S. has received research support and consultancy fees from Novartis Pharmaceuticals Corporation, has served on advisory boards for Novartis, Takeda, Savient, URL Pharma and EnzymeRx, and is/has been a member of a speakers' bureau for Takeda. A.S. has received consultation fees from Novartis Pharma AG, Abbott, Bristol-Myers Squibb, Essex, Pfizer, MSD, Roche, UCB and Wyeth. All other authors have declared no conflicts of interest.

113. EFFICACY OF CANAKINUMAB (ACZ885), A FULLY HUMAN ANTI-INTERLEUKIN -1BETA MONOCLONAL ANTIBODY, IN THE PREVENTION OF FLARES IN GOUT PATIENTS INITIATING ALLOPURINOL THERAPY

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Background: Gout patients initiating urate lowering therapy have an increased risk of flares. Inflammation in gouty arthritis is induced by interleukin (IL)-1β. Canakinumab inhibits IL-1β effectively in clinical studies. This study compared different doses of canakinumab vs colchicine in preventing flares in gout patients initiating allopurinol therapy.
Methods: In this 24 wk double blind study, gout patients (20-79 years) initiating allopurinol were randomized (1:1:1:1:1:1:2) to canakinumab s.c. single doses of 25, 50, 100, 200, 300 mg, or 150mg divided in doses every 4 wks (50 + 50 + 25 + 25 mg [q4wk]) or colchicine 0.5 mg p.o. daily for 16 wks. Primary outcome was to determine the canakinumab dose giving comparable efficacy to colchicine with respect to number of flares occurring during first 16 wks. Secondary outcomes included number of patients with flares and C-reactive protein (CRP) levels during the first 16 wks.
Results: 432 patients were randomized and 391 (91%) completed the study. All canakinumab doses were better than colchicine in preventing flares and therefore, a canakinumab dose comparable to colchicine couldn't be determined. Based on a negative binomial model, all canakinumab groups, except 25 mg, reduced the flare rate ratio per patient significantly compared to colchicine group (rate ratio estimates 25 mg 0.60, 50 mg 0.34, 100 mg 0.28, 200 mg 0.37, 300 mg 0.29, q4wk 0.38; $p \leq 0.05$). Percentage of patients with flares was lower for all canakinumab groups (25 mg 27.3%, 50 mg 16.7%, 100 mg 14.8%, 200 mg 18.5%, 300 mg 15.1%, q4wk 16.7%) compared to colchicine group (44.4%). All patients taking canakinumab were significantly less likely to experience at least one gout flare than patients taking colchicine (odds ratio range [0.22 - 0.47]; $p \leq 0.05$ for all). Median baseline CRP levels were 2.86 mg/L for 25 mg, 3.42 mg/L for 50 mg, 1.76 mg/L for 100 mg, 3.66 mg/L for 200 mg, 3.21 mg/L for

300 mg, 3.23 mg/L for q4wk canakinumab groups and 2.69 mg/L for colchicine group. In all canakinumab groups with median CRP levels above the normal range at baseline, median levels declined within 15 days of treatment and were maintained at normal levels (ULN = 3 mg/L) throughout the 16 wk period. Adverse events (AEs) occurred in 52.7% (25 mg), 55.6% (50 mg), 51.9% (100 mg), 51.9% (200 mg), 54.7% (300 mg), 58.5% (q4wk) of patients on canakinumab vs 53.7% of patients on colchicine. Serious AEs (SAE) were reported in 2 (3.6%; 25 mg), 2 (3.7%, 50 mg), 3 (5.6%, 100 mg), 3 (5.6%, 200 mg), 3 (5.7%, 300 mg), 1 (1.9%, q4wk) patients on canakinumab and in 5 (4.6%) patients on colchicine. 1 fatal SAE (myocardial infarction, not related to study drug) occurred in colchicine group.
Conclusions: In this randomized, double-blind active controlled study of flare prevention in gout patients initiating allopurinol therapy, treatment with canakinumab led to a statistically significant reduction in flares compared with colchicine and was well tolerated.
Disclosure statement: U.A., A.B., G.K., D.R. and P.S. are employees of and have stock options or bold holdings with Novartis Pharma AG. E.M. is a principal investigator for Novartis Pharmaceuticals Corporation. E.N. has received consulting fees from Roche. N.S. has received research grants from Novartis Pharmaceuticals Corporation. A.S. has received consultancy fees from Novartis Pharma AG, Abbott, Bristol-Myers Squibb, Essex, Pfizer, MSD, Roche, UCB and Wyeth. All other authors have declared no conflicts of interest.

Miscellaneous rheumatic diseases

114. JUNIOR DOCTORS' KNOWLEDGE OF THE GUIDELINES FOR MANAGING SUSPECTED SEPTIC ARTHRITIS

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Background: Septic arthritis is a common condition that carries a high degree of mortality and morbidity. Traditionally, however, its management has been shown to be sub-optimal. Various studies have described some or all of: a lack of or delay in joint aspiration, antibiotics being started prior to joint aspiration, blood cultures not being sent, synovial fluid not being sent for crystal analysis, and a lack of or delay in specialist referral. This has often resulted in a muddying of the diagnosis and as a result extended lengths of hospital stay. It has been suggested that at the root of this lies a significant lack of knowledge of the BSR guidelines amongst doctors in medical and surgical specialties. To add to the body of work that exists in this area, I tested this suggestion by surveying the junior doctors in my hospital on their knowledge of the BSR guidelines.
Methods: I devised ten true or false questions based on the BSR guidelines for the management of the hot swollen joint in adults, 2006. I prefaced them with a short clinical vignette ending in the summary, ''The clinical suspicion is high for septic arthritis.'' The questions were then issued to each doctor in the hospital below ST3 level in medicine, surgery and A&E. Some were completed and returned via e-mail, but the majority were done at the end of group teaching sessions. All participants were asked to give their answers without using external resources.
Results: 63 doctors participated from F1 to CT2 grades (22 = F1, 20 = F2, 14 = CT1, 7 = CT2). The majority of F1 and F2 doctors were working in medicine (24) with 10 currently working in surgery and the rest in A&E or GP. 18 of the core trainees were working in medicine, the other 3 working in A&E. See Table 1 for results.
Conclusions: Knowledge of the BSR guidelines is patchy in this group of junior doctors. There is a significant proportion who are unaware that blood cultures and fluid for crystals should always be sent while nearly half are unaware that fluid should be aspirated prior to starting antibiotics. These findings are supportive of the suggestion that a lack of knowledge of the guidelines explains the sub-optimal management reported elsewhere. Given that this is predictive and perhaps representative of poor adherence locally, I have presented these findings, run a joint injection workshop and are introducing a treatment algorithm to ensure best practice.
Disclosure statement: The author has declared no conflicts of interest.

Table 1. Percentage correct answers per question

	F1	F2	CT1/CT2
Treat even in absence of fever	95	90	85
Must aspirate before starting antibiotics	41	65	52
Warfarin is not a contraindication	41	70	81
Refer to Orthopaedics if prosthetic	95	80	76
Not excluded if gram stain negative	95	100	90
Not excluded if culture negative	45	60	71
Always perform microscopy for crystals	72	80	85
Always perform blood cultures	91	80	95
Urate levels are of no diagnostic value	27	40	66
X-ray is of no diagnostic value	45	30	28

115. POLYMYALGIA RHEUMATICA: DIAGNOSIS, PRESCRIBING AND MANAGEMENT IN PRIMARY CARE

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Background: Polymyalgia rheumatica (PMR) is the most common inflammatory rheumatological disorder affecting elderly Caucasians. Studies of polymyalgia rheumatica have centred largely on patients recruited from secondary and specialist care settings yet the majority of patients are diagnosed and managed solely in primary care. In the very few primary care studies undertaken, it has been shown that there is wide variation in practice and established diagnostic criteria are infrequently used. Our study aims to clarify further, and compare with the most up to date guidelines, the diagnostic processes and management of polymyalgia rheumatica in the primary care setting.
Methods: Using the two linked regional databases (Consultations in Primary Care Archive (CiPCA) and Prescriptions in Primary Care Archive (PiPCA) at the Primary Care Sciences department at Keele University, patients with PMR were identified by Read code. Using the latest guidelines, areas for review were identified and the relevant data from the database's frozen consultations, prescription data and investigation results was extracted.
Results: Documentation of symptoms was clearly present in 82.2% of cases with the most common primary symptom being the classical bilateral shoulder pain (45.7%). A documented process of exclusion was seen in just 22.4% of cases and a standard response to steroids was seen in 72.7%. The mean initial dose was 21.5 mg of prednisolone although the modal dose was 15 mg. 22.9% were diagnosed with an ESR of less than 30. The average duration of illness was 19 months ranging from 0 to 96 months. Referral was made in 45.4% of cases although in the great majority of those referred it was unclear why they were referred.
Conclusions: Compared to previous studies, referral rates are higher, initial steroid doses are appropriate and documentation is improving. Clear areas for improvement would include better documentation of a process of exclusion to rule out more sinister pathologies and early referral of patients to specialist care for those who do not fit the ''normal'' PMR picture.
Disclosure statement: The authors have declared no conflicts of interest.

116. THE PREVALENCE OF VITAMIN D DEFICIENCY IN RHEUMATOLOGY OUTPATIENTS PRESENTING WITH ARTHRALGIA, MYALGIA OR FATIGUE

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Background: Vitamin D deficiency is classically associated with childhood ricketts and osteomalacia in adults due to its importance in the maintenance of calcium and phosphate homeostasis. However, over the past few years, low vitamin D levels have been shown to be associated with a various disorders ranging from colorectal cancer, through multiple sclerosis to Type I Diabetes. Within the field of rheumatology, in addition to osteoporosis, vitamin D deficiency is linked to the onset of RA, connective tissue disorders and chronic widespread pain.

The aim of the study was to determine the prevalence of vitamin D deficiency in these patients.
Methods: It is the usual practice of one of our consultants (PH) to check vitamin D status in patients presenting with polyarthralgia, polymyalgia or fatigue regardless of their primary rheumatological diagnosis. 25 hydroxyvitamin D levels were measured in such patients attending our rheumatology clinics in a 3 month period between August and November 2010.