Results: 1040 subjects with 3719 follow-up visits spanning an average of 63.2 weeks were analysed. African Americans and Hispanics comprised 24% and 15%, respectively. Compared to Whites, African Americans and Hispanics had significantly less education ($p<0.001$ for both), significantly less biologic use ($p<0.001$ for both) and significantly less TNF use ($p<0.001$ for both). African Americans had significantly higher RAPID3 scores at enrollment than Whites as well ($p=0.018$).

Switching between TNFi and non-TNFi was recorded in only 9 subjects, with 7 subjects switching from TNFi to non-TNFi. There was no statistical difference between race/ethnic groups in frequency of bDMARD switching, nor within bDMARD class (TNFi class, $p=cc$; non-TNFi class, $p=bb$). bDMARD treatment led to MCI in RAPID3 in 101 (38%) subjects and in more African Americans (29 [48%]) and Hispanics (12 [41%]) than in Whites (49 [37%]) (but not statistically significant).

Conclusions: In our cohort, disparity was seen in bDMARD use between race and ethnic groups but had similar and infrequent biologic switch. Based upon these data, efforts to eliminate biologic use disparity remains paramount and supersedes concerns regarding disparity in biologic switching.

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AB0441 DRUG SURVIVAL AND REASON FOR DROP-OUT IN RHEUMATOID ARTHRITIS PATIENTS WITH A NON-MEDICAL SWITCH FROM ORIGINATOR TO BIOSIMILAR ETANERCEPT – PRELIMINARY DATA FROM A NORWEGIAN MULTICENTER STUDY

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Background: Norwegian rheumatologists are encouraged to prescribe the low-cost biologic DMARDs according to the national tender system. Thus, non-medical switch from the originator drug to its biosimilar is extensively performed. There is a need for more real life data to clarify the clinical outcomes, dropout rates and reasons for these dropouts after a non-medical switch from the originator to biosimilar ETN.

Objectives: To explore drug survival and clinical outcomes in rheumatoid arthritis (RA) patients after a non-medical switch from the originator to biosimilar ETN (SB4) in ordinary outpatient clinics across Norway.

Methods: Herein we present preliminary data collected at one participating centre. Patients were monitored and data were collected by the use of a hospital clinical computer system GoTreatIT Rheuma. The computer system is also used for data collection for the Norwegian national arthritis registry, NorArtritt. Demographic, clinical and treatment data were retrieved (21st of January 2018) from the computer system for the time point of non-medical switch of ETN and the last follow up. Wilcoxon matched-pair signed rank test was used for comparison between the two-time points.

Results: Since April 2016 191 RA patients (mean age 60.8 years, 67% females) underwent a non-medical switch from originator to biosimilar ETN. Mean (SD) observation time for the 163 patients (85.3%) still on biosimilar ETN was 1.23 (0.46) yrs. 28 patients (14.7%) stopped treatment. Among them mean (SD) observation time for the 7 patients (3.7%) in remission was 0.53 (0.33) yrs, for the 10 patients (5.2%) reporting adverse events 0.44 (0.32) yrs and for the 11 patients (5.8%) reporting lack or loss of efficacy 0.44 (0.35) yrs. The adverse events reported was: 1 chest pain, 1 neuropathy, 1 GI reaction, 1 visual impairment, 1 infection, 2 joint stiffness (1 patient went back on ETN SB4) and 3 skin reactions. For all 191 patients no significant change (median [IQR]) from baseline to last observation was seen for DAS28 (2.1 [1.5–2.8] vs 1.9 [1.5–2.5], $p=0.33$), MHAQ (0.3 [0.0–0.7] vs 0.4 [0.1–0.6], $p=0.62$) and patient VAS global (20.0 [10.0–43.0] vs 25.0 [10.0–43.3] mm, $p=0.73$), whereas CRP improved significantly during follow up (2.0 [1.0–5.0] vs 1.0 [1.0–5.5] mg/dl, $p=0.02$). For the subgroup of RA patients who stopped treatment because of lack of efficacy a minor non-significant impairment was observed for DAS28 (2.0 [1.4–2.5] vs 2.6 [1.2–4.0], $p=0.32$), CRP (0.0 [0.0–6.0] vs 3.5 [0.8–13.3] mg/dl, $p=0.66$), MHAQ (0.1 [0.0–0.1] vs 0.5 [0.3–0.5], $p=0.66$) and patient VAS global (20.0 [10.0–30.0] vs 29.0 [17.0–58.5] mm, $p=0.66$).

Conclusions: Our preliminary data indicate that for the majority of patients, a non-medical switch from originator to biosimilar ETN (SB4) was well tolerated with no impairment in disease measures. Whether the reported adverse events were associated to the switch needs to be further studied. In patients who stopped the biosimilar because of lack of effect only a minor numerically increase in disease

measures was seen. Our promising preliminary results need to be confirmed in a large scale study.

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AB0442 LONG-TERM SAFETY AND EFFICACY OF BIOSIMILAR INFLIXIMAB (CT-P13) AFTER SWITCHING FROM ORIGINATOR INFLIXIMAB: RESULTS FROM THE 26-WEEK OPEN LABEL EXTENSION OF A NORWEGIAN RANDOMISED TRIAL

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Background: The NOR-SWITCH study was funded by the Norwegian government to investigate if switching from originator infliximab (INX) to biosimilar CT-P13 is safe in rheumatoid arthritis (RA), spondyloarthritis (SpA), psoriatic arthritis (PsA), Crohn's disease (CD), ulcerative colitis (UC), and chronic plaque psoriasis (Ps).

Objectives: Assessing efficacy, safety, immunogenicity at week 78 in patients on CT-P13 for 78 weeks (maintenance group) vs CT-P13 for 26 weeks (switch group).

Methods: 481 adult patients on stable originator infliximab were randomised 1:1 to continued INX or switch to CT-P13 treatment in the main study¹. All extension participants received CT-P13. The primary endpoint was disease worsening, analysed with logistic regression, adjusted for diagnosis and treatment duration.

Abstract AB0442 – Table 1

Demographic and baseline characteristics (52 w) Number of patients (FAS)	Maintenance group 197	Switch group 183	Data are n (%) or mean (SD)
Age (years)	48.8 (14.9)	48 (14.3)	
Duration of ongoing infliximab treatment (years)	7.7 (3.8)	7.4 (3.5)	
Concomitant immunosuppressive therapy	97 (49%)	75 (41%)	
Rheumatoid arthritis	27 (14%)	28 (15%)	
Spondyloarthritis	38 (19%)	29 (16%)	
Psoriatic arthritis	9 (5%)	11 (6%)	
Crohn's disease	65 (33%)	62 (34%)	
Ulcerative colitis	42 (21%)	38 (21%)	
Psoriasis	16 (8%)	15 (8%)	
Disease characteristics			
DAS 28 RA	2.4 (0.9)	2.8 (0.9)	
DAS 28 PsA	2.1 (1.1)	2.9 (1.8)	
ASDAS (SpA)	1.9 (0.8)	1.7 (0.7)	
Disease worsening Number of patients (PPS)	190	173	Risk difference (95% CI)
All	32 (16.8%)	20 (11.6%)	–5.9% (–12.9–1.1)
Rheumatoid arthritis	9 (34.6%)	6 (22.2%)	–10.5% (–34.6–13.6)
Spondyloarthritis	3 (7.9%)	2 (7.1%)	–0.6% (–13.5–12.2)
Psoriatic arthritis	1 (12.5%)	3 (33.3%)	20.8% (–17.6–59.1)

ASDAS, Ankylosing Spondylitis Disease Activity Score. DAS28, Disease Activity Score in 28 joints.

Results: 380 patients entered the extension trial. Demographic and baseline (52 w) characteristics of the extension study population are shown (table 1). Disease worsening in the study arms (Per Protocol Set, PPS) and in each diagnosis (explorative analyses) are shown (table 1). Generic disease variables, disease specific composite measures, trough drug levels, anti-drug antibodies and reported adverse events were comparable between groups (data not shown).

Conclusions: We found no difference between patients switched from INX to CT-P13 vs those on maintained CT-P13

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