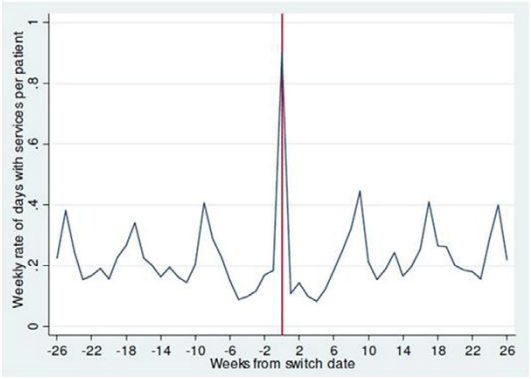
Figure Weekly rate of days with services per patient according to switch date



weekly rate of days with services showed no obvious differences before and after the switch but had a clear 8-week pattern (corresponding to the average infusion interval) (Figure).

The total number of services provided was 19,752 (2,019 of these on the switch date). There were significant increases in the rates before vs after switch for 6 of the 16 service categories, although the mean rates were small: telephone consultations (mean rate 1.0 before vs. 1.2 after), patient guidance (0.5 vs. 0.4), intravenous medication (0.0 vs. 0.1), clinical controls (2.1 vs. 2.3) and clinical investigations (0.3 vs. 0.5), whereas the rate of infliximab treatment decreased (3.1 vs 3.0) (all $p<0.05$, insignificant results not shown).

Conclusions: This analysis showed that there were only small differences in the rates of days with outpatient services and rates of services 6 months before and after the switch from original to biosimilar infliximab. Thus, it is unlikely that the switch is associated with substantially higher cost of health care resources.

References:

[1] Glintborg et al. Arthritis Rheumatol. 2016; 68 (suppl 10).

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THU0649 MANDATORY CHOICE OF FIRST BDMARD IN DENMARK – AN OPPORTUNITY TO STUDY REAL-LIFE EFFECTIVENESS? RESULTS FROM THE DANBIO REGISTRY

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Background: In Denmark, biological treatments (bDMARDs) are tax paid. Since year 2013, The Danish Council for the Use of Expensive Hospital Medicines (RADS) has issued recommendations with annual updates regarding RA patients (pts) initiating biological treatment, dictating a mandatory choice of the cheapest bDMARD (1). Furthermore, the percentage of pts expected to be treated according to the RADS recommendation per year is stated. For pts treated with concomitant methotrexate (MTX) recommendations on first line, first choice bDMARD were: Jan 1th 2013-June 30th 2014: certolizumab pegol (in 80% of pts); July 1th 2014 - June 30th 2015: abatacept (80%); July 1th 2015-June 30th 2016: biosimilar infliximab (CT-P13) (50%). The nationwide Danish DANBIO registry collect data prospectively and covers >90% of adults with rheumatological diseases treated with bDMARDs in routine care (2).

Objectives: To characterize Danish RA pts initiating first line, first choice treatment with a bDMARD in combination with MTX in the three RADS periods and to explore the degree of compliance to RADS recommendations. Furthermore, to investigate differences in baseline characteristics between those pts who were compliant to RADS guidelines and those who were not.

Methods: For each of the three RADS' periods bio-naive pts with RA were identified in DANBIO and compliance to RADS recommendations was assessed. Baseline characteristics of those who started first choice bDMARD treatment according to RADS were compared with those who started another biologic instead. Comorbidities and previous hospitalized infections were identified in the Danish National Patient Registry. Comorbidities from Charlson Comorbidity Index were summarized except category number 7, connective tissue disease.

Results: For all three RADS periods, age, gender, functional status and disease activity were typical for pts with RA. Age was median: 57 years, range 18–88 years and disease duration: 3 years, range 0–54 years. 16–22% of pts had ≥1 comorbidity and 7–9% had ≥1 hospitalized infection the previous year. In each of the three RADS periods, 71%, 66% and 60% of pts followed the RADS recommendations, respectively (Table). The table shows differences between those who started first choice bDMARD treatment according to RADS, and those who did not. Overall, pts who complied to RADS had higher DAS28 and patient VAS global. Characteristics of pts who followed RADS recommendations in the three periods appeared similar.

Conclusions: In this nationwide study of >600 RA pts, pts' clinical characteristics were more heterogeneous than in clinical trials, reflecting routine care. Overall, compliance to recommendations was good. Thus, the national guidelines in Denmark with mandatory choice of the first biological drug may provide an interesting opportunity to study effectiveness of bDMARDs in routine care. This highlights observational studies as a valuable supplement to RCTs.

Table 1: Characteristics of RA pts initiating treatment with first bDMARD in combination with MTX stratified by compliance to the recommendations of RADS or not in the three time periods.

	Certolizumab pegol		Abatacept		CT-P13	
Time periods, MM.YY	01.13-06.14		07.14-06.15		07.15-06.16	
Recommended compliance (%)	80		80		50	
Actual compliance to RADS (%)	71		66		60	
Baseline characteristics	RADS	Not RADS	RADS	Not RADS	RADS	Not RADS
Number of pts	328	135	210	109	200	131
Age (years)	**57**	**58**	57	59	59	56
Female (%)	**71**	**80**	73	71	69	71
IgM-RF positive (%)	61	61	67	69	64	70
Anti-CCP positive (%)	74	73	77	83	70	71
Disease duration (years)	3	5	3	4	**4**	**2**
DAS28	**4.6**	**4.3**	**4.5**	**4.3**	4.6	4.5
HAQ	1.1	1.1	**1.1**	**0.9**	1.0	1.0
Patient global VAS (mm)	**70**	**57**	**73**	**53**	69	67
Comorbidities ≥1 (%)*	**22**	**33**	**16**	**28**	24	20
No. of comorbidities (mean)**	1.3	1.5	**1.2**	**1.6**	1.3	1.4
Hosp. infections ≥1 (%) ***	8	10	7	9	9	9

Variables are medians unless otherwise mentioned. **Numbers in bold:** p<0.05 for comparison between RADS/not RADS, (Mann Whitney and Chi-square test) *From baseline and 10 years back; **In pts with ≥1 comorbidity; *** From baseline and 1 year back; Abbreviations: DAS28 Disease activity score in 28 joints; HAQ health assessment questionnaire; VAS: visual analogue scale

References:

[1] The Danish Council for the Use of Expensive Hospital medicines (RADS), http://www.regioner.dk/media/28308/radsfolder-engelsk.pdf.
[2] Hetland ML. Rehumatology 2011;50:69–77.

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THU0650 THE EFFECT OF ANTI-TNF THERAPY ON WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT IN PATIENTS WITH RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS AND PSORIATIC ARTHRITIS OVER ONE YEAR – REAL LIFE DATA FROM THE CZECH BIOLOGICS REGISTRY ATTRA

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Objectives: To assess the effect of anti-TNF therapy on work productivity using the Work Productivity and Activity Impairment-Specific Health Problem (WPAI-SHP) questionnaire in patients with RA, PSA and AS in the real life setting. In the Czech Republic, anti-TNF-therapy is reimbursed for RA if DAS28>5.1 despite therapy with csDMARDs, for PSA if disease is not "adequately controlled" with csDMARDs, and for AS if BASDAI>4 and CRP/ESR elevated above normal.

Methods: WPAI-SHP scores were collected for all patients enrolled in ATTRA since 2012 at baseline and after 12 months of anti-TNF exposure. Bionäive patients with RA (n=352), AS (n=442) and PSA (n=133) starting anti-TNF therapy with available baseline data on demography, disease duration and physical function, and WPAI-SHP at baseline and at 12 months were included in this analysis. Patients older than 60 years, on maternity leave or students were excluded. Only patients working for pay at baseline were assessed for WPAI-SHP summary scores: absenteeism (mean % work time missed), presenteeism (mean % productivity loss at work), overall work impairment (mean % overall work productivity loss), and activity impairment (mean % productivity loss in regular activities).

Results: Baseline characteristic were significantly different between diagnoses (Table 1). Working status changed significantly only in patients with RA (employed

Table 1

	RA (n=352)	AS (n=442)	PSA (n=133)	p-value*
Female	257 (73.0%)	104 (23.5%)	58 (43.6%)	<0.001 ABC
Disease duration	7.1±5.7	7.0±6.7	7.5±7.2	0.245
Age at start of anti-TNF therapy	47.2±8.9	39.5±8.6	44.4±9.1	<0.001 ABC
HAQ	1.5±0.5	1.2±0.5	1.2±0.6	<0.001 AB

Post-hoc analysis (with Bonferroni correction): statistically significant difference btw groups A) RA vs. AS, B) RA vs. PSA, C) AS vs. PSA. Values or N (%) or mean (SD).

Table 2

Dg.	WPAI-SHP component	Baseline	12 months	Mean change after 12 months	N†	P-value*
RA	Absenteeism	12.8 (27.9)	5.1 (18.5)	7.7 (30.3)	203	<0.001
	Presenteeism	52.1 (21.9)	27.6 (20.9)	24.5 (26.3)	183	<0.001
	Overall work impairment	53.9 (22.8)	28.7 (22.0)	25.2 (26.9)	183	<0.001
	Activity impairment	62.4 (21.4)	36.0 (23.0)	26.4 (27.7)	352	<0.001
AS	Absenteeism	10.6 (25.6)	3.5 (15.8)	7.1 (28.0)	307	<0.001
	Presenteeism	53.1 (22.2)	21.1 (18.0)	32.0 (24.9)	282	<0.001
	Overall work impairment	54.8 (22.6)	21.8 (18.8)	33.0 (25.5)	281	<0.001
	Activity impairment	60.7 (22.1)	27.3 (21.4)	33.5 (26.4)	442	<0.001
PSA	Absenteeism	5.7 (17.3)	4.2 (18.4)	1.5 (24.6)	90	0.135
	Presenteeism	43.9 (24.0)	15.3 (16.2)	28.6 (24.5)	84	<0.001
	Overall work impairment	45.2 (25.0)	15.9 (16.8)	29.3 (25.1)	84	<0.001
	Activity impairment	57.4 (24.6)	26.2 (21.3)	31.2 (26.5)	133	<0.001

†N = Number of assessed patients. Values are mean % (SD). *Wilcoxon paired test for difference between baseline and 12 months within each WPAI score.

69→64%, p=0.013), but not in AS (77→78%) or PSA (77→73%). In patients employed for pay both at baseline and after 12 months, all WPAI-SHP scores improved significantly over one year of anti-TNF therapy (Table 2).

Conclusions: In the real life setting of the Czech Republic, anti-TNF therapy effectively reduced absenteeism, presenteeism, activity impairment and work impairment over one year in employed patients with RA, AS and PSA.

Disclosure of Interest: None declared

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THU0651 SHOULD WE REDUCE THE DOSE OF BIOLOGICAL THERAPY TO ALL PATIENTS WITH INFLAMMATORY ARTHRITIS ACHIEVING SUSTAINED THERAPEUTIC GOAL?

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Background: Dose tapering of biological therapies (BT) in patients with rheumatoid arthritis (RA) or spondyloarthritis (SpA) is frequent in Spain. However, there is variability in BT optimization (BTO). So, Spanish Society of Rheumatology published in 2015 recommendations on how to optimize BT (1). Nevertheless, there is no solid evidence on which patient profiles BTO is appropriated.

Objectives: To develop appropriateness criteria for BTO in patients with RA, axial SpA (axSpA) or peripheral SpA (pSpA)

Methods: The RAND/UCLA appropriateness method was used. Five rheumatologists experienced in RA and/or SpA clinical research selected and defined the variables considered relevant when deciding reduction of BT in order to define patient profiles. Ten BT experienced rheumatologists anonymously rated 1 (completely inappropriate) to 9 (completely appropriate) each profile after reading evidence synthesis. Then, in a meeting, classification variables and profiles with disagreement were revised and all profiles were scored again. Profiles with a median score >6 were considered appropriate, those with a median score <3.5 were considered inappropriate and the remaining uncertain. In addition, a study of the prevalence of these profiles was performed in 9 Spanish hospitals.

Results: Combining the options of variables 2,304 different profiles were obtained for RA, 768 for axSpA, and 3,072 for pSpA. 327 (14.2%) profiles in RA, 80 (10.4%) in axSpA, and 154 (5%) in pSpA were considered appropriate for BT dose reduction. By contrast, 749 (53.3%) profiles in RA, 270 (54.4%) in axSpA, and 1243 (54.5%) in pSpA were considered inappropriate. The remaining profiles were considered uncertain. In the preliminary study to determine profiles prevalence, we collected information from 242 RA, 171 axSpA and 172 pSpA patients that underwent BTO. We found that BTO was performed appropriately in 23% RA, 67% axSpA and 61% pSpA patients. BTO was indicated in uncertain profiles in 67% RA, 23% axSpA and 37% pSpA patients. Only in RA we detected BT dose reduction in patient profiles considered inappropriate (2%).

Conclusions: Appropriateness criteria for BT dose reduction in three inflammatory conditions were developed and the preliminary prevalence study suggests that BTO was wisely applied. However, further research in this field is needed to determine the real prevalence of clinical profiles of patients undergoing BTO in daily clinical practice and validate these criteria in real life.

References:

[1] Gonzalez-Alvaro I et al. Rheumatology 2015; 54: 1200–1209.

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THU0652 ASSESSMENT OF BIOSIMILARS USING REAL WORLD DATA: THE COMPLEXITY OF CHOOSING A COMPARATOR AND UNDERSTANDING UPTAKE

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Background: The introduction of biosimilars has been linked with concerns regarding how to best monitor their similarity vs. the originator product using real world data.

Methods: Data from the Swedish Rheumatology Quality register (SRQ) was used to identify all patients with rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatric arthritis (PsA), and other spondyloarthropathy (SpA), who started a treatment with infliximab (originator Remicade or biosimilars Remsima or Inflectra) between 1st Mar 2015 and 30th Sept 2016 or with etanercept (originator Enbrel or biosimilar Benepali) between 1st April 2016 and 30th Sept 2016.

Results: During the study period, a total of 1833 patients started an infliximab treatment and 1793 started etanercept. These patients were either bDMARD-naïve (patients without a history of any biological treatment), non-medical switchers (patients who switched from the originator product), or patients who had a history of a previous (but not the same) bDMARD (Table 1). These three groups were not evenly distributed across originators or biosimilars, and had different baseline demographic and disease characteristics.

The uptake in terms of *treatment starts* was faster for Benepali (it covered more than 90% of this part of the etanercept market after only 3 months) as compared to Remsima and Inflectra (together they accounted for 88% of this section of the infliximab market after 10 months). The uptake of biosimilars in terms of proportion of all patient *on treatment* was, at the end of September 2016, 27%

Table 1. Number of patients starting infliximab (from 1 March 2015 to 30 September 2016) or etanercept (from 1 April 2016 to 30 September 2016) originator or biosimilar, by line of treatment

	Infliximab		Etanercept	
	Originator	Biosimilars	Originator	Biosimilar
Total	570	1263	186	1607
Bio- naïve	379 (66%)	508 (40%)	89 (48%)	581 (36%)
Non-medical switchers	–	524 (42%)	–	710 (44%)
Switchers from other biologics	191 (34%)	231 (18%)	97 (52%)	316 (20%)

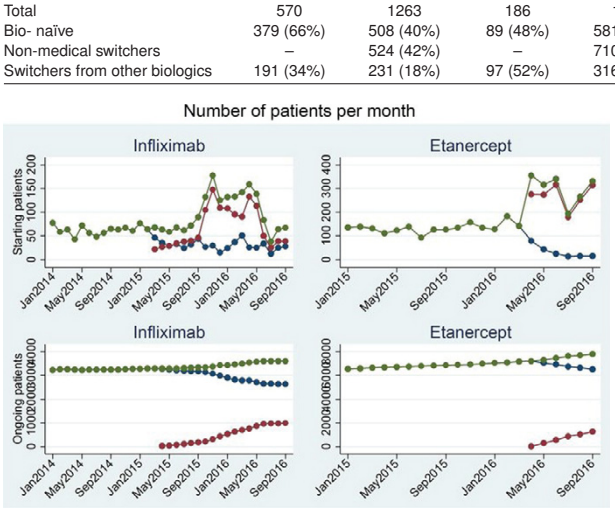

Figure 1. Number of patients *starting*, and *on*, respectively, infliximab or etanercept by month. Green: total, red: biosimilar, blue: originator.