Table 1. Pregnancy outcomes by disease

Main diagnosis	N, %	Gest age at delivery (weeks)	Miscarr	FGR	PE	Preterm births	Flares in preg	Flares in PP
SLE	116, 32.9	38±2.3	13/110, 11.8	6/82, 7.3	5/78, 6.4	15/76, 21.1	16/92, 17.4	5/79, 6.3
SpA	60, 17	39±2.6	2/55, 3.6	5/44, 11.4	1/45, 2.2	5/40, 12.5	18/40, 45	5/23, 21.7
RA	51, 14.4	39±1.2	6/49, 12.2	1/35, 2.9	1/33, 3	1/29, 3.4	10/37, 27	7/30, 23.3
Vasculitis	25, 7.1	38±1.8	1/24, 4.2	1/21, 4.8	0/19, 0	4/21, 19	7/23, 30.4	2/17, 11.8
Primary APS	22, 6.2	38±1.6	3/22, 13.6	1/17, 5.9	1/16, 6.3	2/16, 12.5	NA	NA
JIA	17, 4.8	38±2.5	1/17, 5.9	0/12, 0	0/11, 0	4/12, 33.3	2/13, 15.4	1/8, 12.5
UCTD	15, 4.2	39±1.5	2/15, 13.3	0/11, 0	1/10, 10	1/11, 9.1	0/15, 0	0/15, 0
Primary Sjögren Syndrome	12, 3.4	39±1.4	0/11, 0	0/9, 0	0/10, 0	1/9, 11.1	1/8, 12.5	0/6, 0
Others	35, 9.9	38±2.3	4/31, 12.9	2/20, 10	1/18, 5.6	3/18, 16.7	4/27, 14.8	1/22, 4.5
Total	353, 100	38±2.2	32/334, 9.6	16/251, 6.4	10/240, 4.2	36/232, 15.5	58/255, 22.7	21/200, 10.5
Secondary diagnosis								
APS	27	37±2.7	8/26, 30.8	5/16, 31.3	2/12, 16.7	5/15, 33.3	NA	NA
Sjögren Syndrome	9	37±2.5	1/9, 11.1	1/7, 14.3	0/7, 0	3/6, 50	NA	NA

Legend - gest: gestational; miscarr: miscarriages; NA – not applicable; PP: postpartum; preg: pregnancy; UCTD - Undifferentiated connective tissue disease. Continuous variables are presented as mean±SD. Categorical variables as n/mN, % - modified(m)/N stands for total N – (not applicable+missing data); *Others* accounts for diagnosis with N≤6, such as APS non criteria, mixed connective tissue disease, myositis, overlap syndromes, Still's disease and systemic sclerosis.

Conclusion: In pregnant women with RD, it is of vital importance to be aware of the increased risk for APO. In our cohort, APS and SLE were the conditions most associated with APO, while SpA and RA were responsible for most maternal flares. Nevertheless, the majority of these pts, surveilled by a multidisciplinary team, had successful gestations.

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FRI0516

FACTORS ASSOCIATED WITH DECREASED CERVICAL CANCER SCREENING IN WOMEN WITH SYSTEMIC LUPUS ERYTHEMATOSUS

S. Bruera¹, R. Zogala², X. Lei³, X. Pundole³, H. Zhao³, S. Giordano³, J. Hwang³, M. Suarez-Almazor³. ¹Baylor College of Medicine, Houston, United States of America; ²Community Hospital - Grand Valley Rheumatology, Grand Junction, United States of America; ³University of Texas MD Anderson Cancer Center, Houston, United States of America

Background: Systemic lupus erythematosus (SLE) is a chronic autoimmune disease that carries an increased risk for both viral illnesses and malignancies, including a greater risk for both human papilloma virus (HPV) infection and cervical cancer. Due to this increased risk, the American Society of Colposcopy and Cervical Pathology guidelines for SLE patients recommend more frequent cervical cancer screening. Few studies have examined patient characteristics associated with decreased cervical cancer screening in patients with autoimmune disease, specifically SLE.

Objectives: To estimate cervical cancer screening rates in women with recently diagnosed SLE, and to identify characteristics associated with decreased screening.

Methods: We identified women with an initial diagnosis of SLE in the United States MarketScan Commercial Claims and Encounter (CCA, age 18-64) administrative claims database. We included patients with at least three claims with a lupus diagnosis (first and last at least >90 days apart), no lupus claims within the year before initial claim, and who had been on antimalarial drugs for at least 90 days. We excluded all patients with a previous claim for hysterectomy.

Cervical cancer screening was ascertained using diagnosis and procedure codes within 1 year before and 2 years after the first SLE claim. Our covariates included the year of first SLE claim (2001-2014), age at first SLE claim, comorbidity score, insurance type, geographical region, and prescriptions for multiple types of corticosteroids. Control patients included age-matched females without autoimmune

disease. Univariate comparison and multivariate logistic regression models were built to evaluate determinants of screening.

Results: We included 4,316 SLE patients (median age 45) and 86,544 control patients. The screening rate in SLE patients was 73.4% vs 58.5% in the controls ($P < 0.001$). The screening rate was 71% in 2001, increased to 75% in 2004, then decreased to 70% in 2014 (trend $P = 0.005$). In the multivariate model the following factors were associated with decreased cervical cancer screening: year of first SLE claim 2012-2014 versus 2001-2005 (odds ratio (OR) 0.67, 95% confidence interval (CI) 0.53 – 0.84, $P < 0.001$); older age 61-64 versus 21-30 (OR 0.27, 95% CI 0.19 – 0.39, $P < 0.001$); comorbidity score of ≥ 2 versus < 2 (OR 0.71, 95% CI 0.6 – 0.83, $P < 0.001$); and use of corticosteroids for ≥ 90 days versus < 90 days (OR 0.73, 95% CI 0.59 – 0.9, $P = 0.003$). Insurance type and geographical region were not associated with cervical cancer screening.

Conclusion: About three quarters of women with SLE underwent cervical cancer screening within 3 years of their first lupus claim, at higher rates than controls. However, there was a concerning downward trend in screening rates in recent years. In addition, higher risk populations for cervical cancer (older age, increased comorbidities, and longer duration of corticosteroids) had lower screening rates. These findings highlight the need to enhance education for healthcare providers to improve utilization of screening in women with SLE at high risk of cervical cancer.

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FRI0517

POSSIBLE EARLY DETECTION OF ADVERSE EVENTS USING A STRUCTURED, STANDARD, 60-SYMPTOM CHECKLIST ON A MULTIDIMENSIONAL HEALTH ASSESSMENT QUESTIONNAIRE (MDHAQ)

K. Schroeder¹, S. Abu Mehzen¹, I. Castrejon², T. Pincus¹. ¹Rush University, Rheumatology, Chicago, United States of America; ²Gregorio Marañón Hospital, Rheumatology, Madrid, Spain

Background: Adverse events of medications are reported to account for 5% of hospital admissions in the USA, including 10% in the elderly, despite extensive warnings to patients by health professionals and pharmacies concerning the problem. Some adverse events are relatively obvious, such as a severe rash or severely abnormal laboratory test. However, many adverse events are common symptoms, such as headache or fatigue, which may not necessarily be recognized as adverse events, particularly in elderly patients with many comorbidities. In clinical trials and other clinical research, a structured, standard, protocol-driven symptom checklist is recorded according to the "scientific method." In routine care, by contrast, recognition and recording of adverse events is elicited by health professionals at patient encounters or contact initiated by patients between visits, as "subjective" medical history information, which may be highly variable. Use of a standard symptom checklist on an electronic patient questionnaire has been reported in oncology, pulmonology and other specialties, but not in rheumatology. A multidimensional health assessment questionnaire (MDHAQ) includes a standard 60-symptom checklist, to recognize comorbidities, provide a review of systems, and serve on a fibromyalgia assessment screening tool (FAST3) as a clue to identify patients with fibromyalgia. The MDHAQ 60-symptom checklist can identify new symptoms after initiation of a medication which may be adverse events.

Objectives: To analyze an MDHAQ 60-symptom checklist as a cost-effective approach to recognize medication-associated adverse events.

Methods: All patients at one site complete an MDHAQ at each visit, which includes a standard, structured 60-symptom checklist, in addition to RAPID3 (routine assessment of patient index data) and FAST3. Paper MDHAQs from routine care are scanned into an Epic electronic medical record (EMR) and copied into a data repository for retrospective analyses. A list of common adverse events of many specific DMARDs (disease-modifying antirheumatic drugs) and biological agents used to treat rheumatoid arthritis (RA) was compiled from websites of the FDA, pharmaceutical companies, and Up-to-date. Most listed symptoms are found on the structured MDHAQ 60-symptom checklist. A retrospective review of scanned MDHAQs at the first visit was conducted to recognize the presence or absence of self-reported symptoms which were listed as common adverse events for specific DMARDs on the MDHAQ 60-symptom checklist, using simple descriptive statistics. Only methotrexate (Mtx) is presented here due to space limitations.

Results: All symptoms listed as adverse events of specific DMARDs were reported at higher frequencies in 379 DMARD-treated RA patients or 153 Mtx-treated patients, compared to 149 DMARD-naïve patients (Table). More than 30% of DMARD-treated patients reported headache and/or unusual fatigue, 27% anxiety; 10-20% cough, dizziness, hair loss, nausea, skin rash or hives,

Symptom listed on MDHAQ/MEDI60	DMARD naïve N=149 (28%)	DMARD treated N=379 (72%)	Methotrexate N=153 (29%)
Headache	28%	36%	36%
Unusual fatigue	31%	33%	34%
Anxiety	23%	27%	
Cough	16%	18%	
Dizziness	14%	18%	20%
Hair loss	10%	17%	19%
Nausea	11%	13%	18%
Skin rash or hives	11%	14%	13%
Stomach pain/cramps	9%	16%	15%
Eye problems	9%	13%	14%
Anorexia/weight loss	10%	16%	17%
Diarrhea	5%	9%	8%
Fever	5%	8%	7%
Mouth sores	3%	7%	8%

stomach pain or cramps, eye problems, and/or weight loss; and 5-10% diarrhea, fever, and/or mouth sores (Table). Similar proportions were seen for Mtx-treated patients, although anxiety and cough were not listed as specific adverse events.

Conclusion: The MDHAQ symptom checklist may prove valuable to detect adverse events of high-risk medications, including on an electronic MDHAQ, which could be completed at home for 12 weeks after initiation of a new medication as a cost-effective approach for early detection of adverse events.

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Dr. Pincus holds a copyright and trademark on MDHAQ and RAPID3 for which he receives royalties and license fees from profit-making organizations, all of which are used to support further development of quantitative clinical measures for patients and health professionals.

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FRI0518

BIOSIMILAR INFlixIMAB THERAPY IN RHEUMATOID ARTHRITIS, SPONDYLOARTHRITIS AND PSORIATIC ARTHRITIS: A LONG-TERM FOLLOW-UP STUDY

H. Marotte¹, A. Tamzali², B. Fautrel³. ¹University Hospital of Saint-Étienne, Saint-Priest-en-Jarez, France; ²Pfizer, Paris, France; ³University Hospitals Pitié Salpêtrière - Charles Foix, Paris, France

Background:

Objectives: REFLECT study has been carried out to assess in real life the use of CT-P13, the first monoclonal antibody biosimilar to infliximab (IFX) approved in France. Long-term real-life data on CT-P13 use are limited in patients (pts) suffering from rheumatic diseases and inflammatory bowel diseases.

Methods: REFLECT is a multicenter, prospective, observational study conducted in France which aims to describe characteristics of pts' receiving CT-P13 and to assess its safety and effectiveness in real-life conditions. Eligible pts for inclusion were pts (≥ 6 years old) with RA, axSpA, PsA, and inflammatory bowel disease treated with CT-P13. IFX naïve pts (IFX-N) or those having switched from IFX originator to CT-P13 were enrolled (IFX-S). An intermediate result in pts with rheumatic diseases using descriptive statistical analyses from inclusion after 18-month-follow-up period are described below.

Results: From 19 October 2016 to 31 January 2019, 1321 pts were included by 70 centres, and 616 pts with rheumatic diseases were analysed: 132 RA (25.0% males; mean age: 61.5 ± 10.5; median time since diagnosis: 12.9 years), 398 axSpA (59.0%; 48.0 ± 13.1 years; 10.7 years, respectively), and 86 PsA (41.9%; 53.0 ± 14.1 years; 10.3 years). Previous bDMARDs other than IFX were reported in 40.1%, 42.1% and 47.4% of RA, axSpA and PsA pts, respectively. More than 1/3 of pts switched from the IFX originator to CT-P13 (40.2% of RA, 42.7% of axSpA and 35.5% of PsA). At the first administration of CT-P13, the majority of IFX-N pts had active disease (92.0% of RA, 76.4% of axSpA and 55.0% of PsA) compared to IFX-S pts (39.5% of RA, 23.1% of axSpA and 26.3% of PsA). At the first infusion of CT-P13, the median DAS28 scores were 4.8 and 2.4 for RA pts in IFX-N and IFX-S pts, and 4 and 2.2 for PsA pts, respectively. In axSpA pts, the median BASDAI at baseline were 5.6 and 2.4 and the median BASFI was 5.3 and 2.8 in IFX-N and IFX-S pts, respectively. From the first administration of CT-P13 to 18 months follow-up the median DAS 28 decreased (-1 point) in both IFX-N pts and IFX-S for RA pts; for axSpA pts the BASFI and BASDAI scores decreased by -2 and -1, respectively in IFX-N and remained stable in IFX-S.

The analysis of pts suffering from PsA has not been reported due to the small number of patients with a follow-up at 18 months (4 IFX-N pts and 1 IFX-S pts).

Table 1. Reasons for treatment withdrawing

	RA		Ax Spa		PsA	
IFX pts (N)	IFXn (N=16)	IFXs (N=9)	IFXn (N=28)	IFXs (N=30)	IFXn (N=5)	IFXs (N=6)
Missing	0	0	1	0	0	0
Remission	0 (0.0%)	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Therapeutic failure	9 (56.3%)	3 (33.3%)	18 (56.3%)	19 (63.3%)	3 (60.0%)	4 (66.7%)
Intolerance	2 (12.5%)	1 (11.1%)	3 (11.1%)	2 (6.7%)	0 (0.0%)	0 (0.0%)
Other	5 (31.3%)	3 (33.3%)	6 (22.2%)	9 (30.0%)	2 (40.0%)	2 (33.3%)

Table 2. Safety data

	RA (N=132)	ax Spa (N=398)	PsA (N=86)
Patients with at least one adverse event (AE)	49 (37.1%)	141 (35.4%)	25 (29.1%)
Patients with at least one serious AE	11 (8.3%)	19 (4.8%)	1 (1.2%)
Patients with at least one allergic infusion reaction†	3 (2.3%)	9 (2.3%)	-
Patients with at least one infection‡	3 (2.3%)	4 (1.0%)	1 (1.2%)

† Including acute and delayed hypersensitivity reactions

‡ Including severe infections, tuberculosis, opportunistic infections, hepatitis.

78.8%, 82.9% and 87.2% remain on treatment with CT-P13 in RA, AxSpA and PsA pts respectively. The reasons for treatment withdrawing are reported in table 1.

The safety data are presented in Table 2.

Conclusion: The results from this long-term follow-up period show that CT-P13 was effective in inducing and maintaining remission in both naïve and switched patients. This real-life study did not highlight any new safety concerns.

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FRI0519

IMPROVING RHEUMATOID ARTHRITIS COMPARATIVE EFFECTIVENESS RESEARCH USING THE TARGET TRIAL EMULATION FRAMEWORK: A SYSTEMATIC REVIEW

S. S. Zhao¹, H. Lyu², D. Solomon², K. Yoshida². ¹University of Liverpool, Institute of Ageing and Chronic Disease, Liverpool, United Kingdom; ²Brigham and Women's Hospital, Division of Rheumatology, Inflammation, and Immunity, Boston, United States of America

Background: Methods used in observational comparative effectiveness research (CER) are highly variable. Target trial emulation is an intuitive design approach that encourages researchers to formulate their question as a hypothetical randomised controlled trial (RCT), or the "target trial". Using observational data to emulate the target trial helps avoid common biases and has been shown to better align results with actual RCTs.

Objectives: We systematically reviewed observational CER studies in rheumatoid arthritis to provide examples of design issues that might have been avoided by using target trial emulation.

Methods: We searched for head-to-head effectiveness comparisons of biologic DMARDs in RA. Study designs were reviewed for components of target trial emulation: 1) eligibility criteria, 2) treatment strategies, 3) assignment procedures, 4) follow-up period, 5) outcome, 6) causal contrasts of interest (i.e., intention-to-treat or per-protocol effect), and 7) analysis plan. Reported methods were taken as the "emulation" of a corresponding target trial, to assess design issues that might introduce bias.

Results: We found 31 CER studies, the majority of which had one design issue belonging to one of the 7 protocol components (Table 1). The most common issues were: 1) 17 out of 31 studies used post-baseline information to define baseline eligibility (e.g. requiring ≥1 follow-up), which can bias results; 2) 26 out of 31 studies did not declare their causal contrast of interest, which is often made difficult by issue 1 and impacts data analysis and interpretation; and 3) 9 out of 31 studies used statistical selection of confounders rather than pre-defining them, which can also introduce bias (e.g. through adjustment of collider or intermediate variables).