THU0677 OUTCOME MEASUREMENT INSTRUMENTS FOR SAFETY IN RHEUMATOLOGY: A SCOPING REVIEW OF AVAILABLE INSTRUMENTS TO INFORM THE OMERACT SAFETY WORKING GROUP

L. Klokker[1], T. Woodworth[2], D.E. Furst[2], P. Tugwell[3], D. Devoe[4], P. Williamson[5], C.B. Terwee[6], M.E. Suarez-Almazor[7], V. Strand[8], A.L. Leong[9], N. Goel[10], M. Boers[11], P.M. Brooks[12], L.S. Simon[13], R. Christensen[1] on behalf of OMERACT working group. *[1]The Parker Institute, Bispebjerg & Frederiksberg Hospital, Copenhagen, Denmark; [2]David Geffen School of Med., Division Rheumatology, UCLA, Los Angeles, United States; [3]Dept of Medicine, School of Epidemiology, Public Health and Community Medicine, University of Ottawa, Ottawa; [4]Department of Medicine, University of Calgary, Cumming School of Medicine, Calgary, Canada; [5]Institute of translational medicine, University of Liverpool, Liverpool, United Kingdom; [6]Department of Epidemiology and Biostatistics, the EMGO Institute for Health and Care Research, VU University Medical Center, Amsterdam, Netherlands; [7]Section of Rheumatology and Clinical Immunology, University of Texas MD Anderson Cancer Center, Houston; [8]Div Imm/Rheum, Sanford University, San Fransisco; [9]Healthy Motivation, Global Alliance for Musculoskeletal Health, Bone and Joint Decade, Santa Barbara; [10]Advisory Services, Strategic Drug Development, Quintiles IMS, Morrisville NC, United States; [11]Department of Epidemiology and Biostatistics, Amsterdam Rheumatology and immunology Center, VU University Medical Center, Amsterdam, Netherlands; [12]Centre for Health Policy Melbourne School of Population, Global Health University of Melbourne, Melbourne, Australia; [13]SDG LLC Cambridge, Cambridge MA, United States*

Background: International scientific networks have raised concerns about inadequate reporting of safety outcomes in randomised trials and systematic reviews. Outcome Measures in Rheumatology (OMERACT) has previously developed an adaptation of the US National Cancer Institute (US NCI) Common Terminology Criteria for Adverse Events (CTCAE), the RCTC (Rheumatology Common Toxicity Criteria) to collect adverse events in rheumatology clinical trials. To respond to the need to also report safety outcomes from the patient perspective, the Safety Working Group is developing a core outcome set, followed by a core outcome measurement set. A scoping review of available instruments for measuring safety outcomes is needed to inform this work.

Objectives: To identify candidate measurement instruments for safety outcomes in rheumatology clinical trials.

Methods: A systematic search was performed in the MEDLINE database (via PubMed) in January 2017 using MeSH terms covering synonyms for adverse events, rheumatology and measurement instruments and the Boolean operator AND to combine them. Full-text articles about the development or evaluation of instruments for measuring safety in rheumatology were eligible. One reviewer (LK) screened for eligibility based on title and abstracts. Two reviewers (LK and RC) screened the full text articles.

Results: Of 434 unique references identified, 19 were read in full-text, and 8 were included (see figure). The instruments identified were: Glucocorticoid Toxicity Index (GTI), Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC), Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA)-SLEDAI flare index (cSFI), the BioSecure questionnaire, Rheumatology Common Toxicity Criteria (RCTC), OMERACT 3x3, and the Stanford Toxicity Index (STI). These instruments were specific for substance (GTI, BioSecure questionnaire), setting (PREOS-PC), condition (cSFI), or not fully validated (RCTC, OMERACT 3x3, STI).

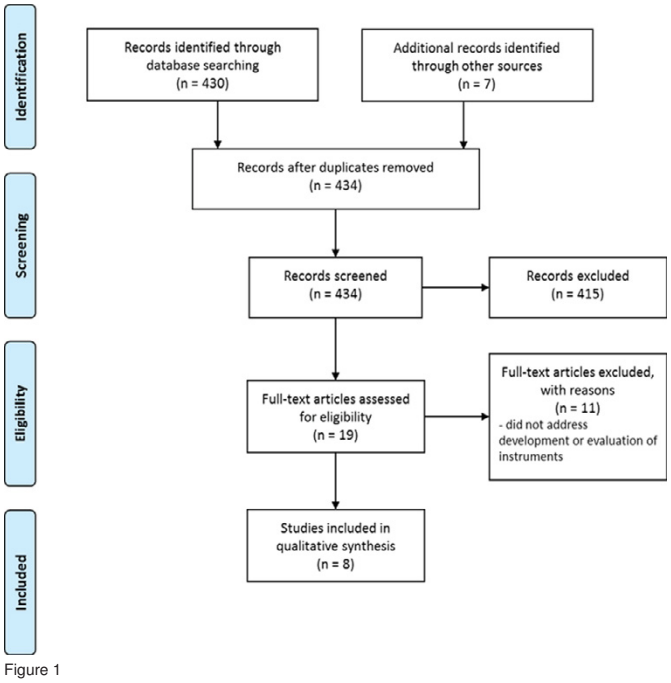


Figure 1

Conclusions: The instruments identified are either too specific, or require further development/evaluation, for the purpose of standardizing measurement of safety in rheumatology clinical trials. Thus, we will proceed to gain consensus on the domains that must be measured to develop a core outcome set.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.6141

THU0678 EXPRESSION OF ADHESION MOLECULES CD44V3 AND CD44V6 ON T CELLS IN SLE PATIENTS: CORRELATION WITH CLINICAL PHENOTYPE AND DISEASE ACTIVITY

L. Novelli[1], C. Barbati[1], F. Ceccarelli[1], C. Perricone[1], F.R. Spinelli[1], C. Alessandri[1], G. Valesini[1], R. Perricone[2], F. Conti[1]. *[1]Lupus Clinic, Sapienza University of Rome, Italy; [2]Rheumatology, Allergology and Clinical Immunology, Tor Vergata University, Rome, Italy*

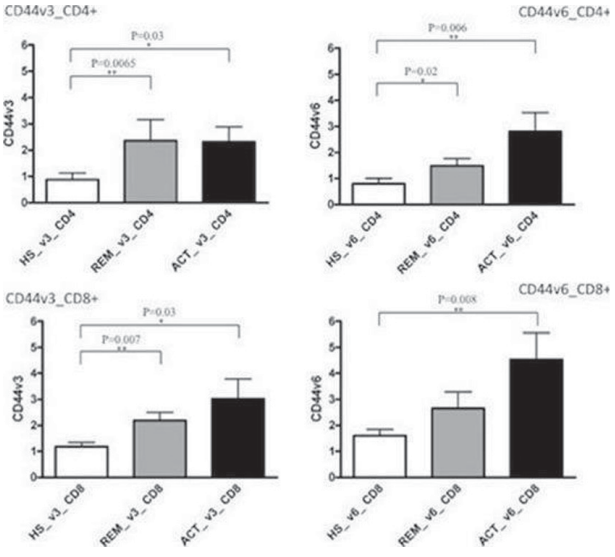
Background: Adhesion molecule CD44 enables T lymphocytes' adhesion to endothelium. During inflammation, increased expression of CD44 contributes to T cell migration into target organs. Infiltration of peripheral tissues is crucial in the development of SLE organ damage and the different isoforms of CD44 seem to be involved in this process. Both CD44v3 and CD44v6 isoforms have been found in kidney biopsies of SLE patients, and CD44v3 in the skin only[1,2]. A higher expression of CD44v3 and v6 has been identified on T cells from SLE patients compared to healthy subjects (HS) and the expression levels seem to correlate with disease activity[3].

Objectives: The aim of this study was to investigate the expression of the CD44v3/v6 isoforms on T cells of SLE patients and their correlation with disease activity and clinical phenotype.

Methods: We enrolled 23 patients (23F, mean age±SD 45.7±13 years, mean disease duration±SD 13±8years) affected by SLE according to the 1997 ACR criteria, and 14 HS (14F, mean age±SD 34.28±12.7 years). Disease activity was measured by SLEDAI-2K. 10 patients were in remission (SLEDAI-2K=0) and 13 patients had an active disease (SLEDAI-2K≥4). Expression of CD44v3 and v6 on T cells was determined by flow cytometry analysis.

Results: Expression of CD44v3 and v6 was significantly higher in active and remission patients compared to HS on CD4+ and CD8+ T cells. SLE patients with active disease showed a trend of major expression of CD44v3 and v6 on CD4+ and CD8+ cells compared to patients in remission (Fig.1). CD44v3/CD44v6 expression ratio on CD4+ and CD8+ T cells was shifted towards isoform v3 on CD4+ cells and towards isoform v6 on CD8+ cells in SLE patients in remission and HS. In active disease this ratio was shifted towards isoform v6 on both T cells populations (Table 1). By using a ROC curve analysis, CD44v6 on CD4+ T cells resulted the most sensitive and specific one (sensitivity 82.6%, specificity 78.6%). Finally, we observed a significant correlation between CD44v3 on CD4+ cells and skin involvement (P=0.027, r=0.632).

Ratio	CD4 CD44v3/CD4 CD44v6	CD8 CD44v3/CD8 CD44v6
Healthy subjects	1.14	0.74
SLE SLEDAI-2k=0	1.58	0.82
SLE SLEDAI-2k≥4	0.82	0.67



Conclusions: Our study confirms previous evidences suggesting a higher expression of CD44v3 and v6 on T cells from SLE patients compared to HS. Higher expression of CD44v3 and v6 on patients with active disease suggests their possible use as biomarkers of disease activity. The good specificity and sensitivity of CD44v6 on CD4+ T cells, and the shift of the ratio towards this