anti-DNase I concentrations were evaluated by conventional ELISA, as described elsewhere [1]. The beads were synthesized using original technique [2], modified ELISA and recovery of the beads for repeating use was performed according to the previously published protocols [2]. Antibody concentrations were expressed as relative optical density units (ODU). The cutoff values for conventional and modified ELISA were 0.061 and 0.057 ODU, respectively. All the means and operation characteristics were expressed as values (95% confidence intervals). Differences were considered significant when $p<0.05$.

Results: Mean anti-DNase I concentrations in SLE patients (negative and positive together) were 0.088 (0.031–0.145) and 0.079 (0.033–0.125) ODU for conventional and modified ELISA, respectively; in the control group they were 0.068 (0.020–0.116) and 0.063 (0.019–0.107) ODU, respectively. Differences within these couples were not significant. Diagnostic sensivity and specificity of modified ELISA were 64.74 (53.09–76.39) and 85.01 (72.95–97.07)%, coinciding with those for conventional ELISA. LOQ for the modified ELISA was slightly lower than for the conventional one. Accuracy and repeatability of modified ELISA were also insignificantly higher than those for conventional approach. There was no substantial change in all the parameters of modified ELISA after single recovery of beads.

Conclusions: The newly developed ELISA for anti-DNase I antibodies was demonstrated to have equivalence or advantage in some analytical parameters over conventional ELISA. Considering some economic and maintenance benefits, our innovation can be an alternative tool to improve SLE diagnostics.

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THU0671 CAN AN INNER DISPOSABLE GLOVE BE USED UNDER AN ELECTROGONIOMETRIC GLOVE FOR MEASURING FINGER MOVEMENT WITHOUT LOSS OF ACCURACY?

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Background: Improving joint mobility is an important outcome for patients with arthritis, but finger joint range of motion is rarely measured in clinic. Electronic gloves with movement sensors have been developed to measure joint movement accurately and it is now possible to assess dynamic mobility of the finger joints. However these gloves are expensive and it is likely that when carrying out measurements in the patient population they would be used with inner disposable gloves to avoid nonsocomical infection. Establishing accuracy and usability of electronic gloves whilst wearing disposable inner gloves is therefore an important pre-requisite for studies in patients with arthritis.

Objectives: To establish the accuracy and repeatability of measurements of finger movement obtained using two different electrogoniometric gloves worn with and without an inner disposable glove.

Methods: We used two different types of electrogoniometric glove for the purpose of this study. One is the commercially available 5DT dataglove 14 Ultra (5DT, 2011) and the other was produced to our specifications by Tyndall National Institute, University College Cork. We called this the “IMU glove”. We developed a graphical interface for both devices to facilitate detailed evaluation of joint movement in each finger. Both gloves were tested using a protocol adapted from Dipietro, Sabatini, & Dario, (2003).

Results: Table 1 displays comparison of Coefficient of Variation (CV) readings for both data gloves. Figure shows this information graphically.

Sensor	No surgical glove		Surgical glove underneath	
	5DT	IMU	5DT	IMU
Index MCP	2.97	2.86	3.22	3.88
Middle MCP	7.01	6.77	9.02	6.39
Ring MCP	6.10	4.37	6.28	4.32
Little MCP	24.17	6.07	9.55	8.25
Index PIP	1.96	9.72	2.92	14.69
Middle PIP	4.40	10.29	2.98	12.53
Ring PIP	5.38	9.95	5.00	11.03
Little PIP	9.11	3.71	10.07	5.46

Results show no significant change for 5DT angular readings with and without a surgical glove worn underneath the data glove. Results for PIP sensors show an improvement in repeatability with a surgical glove. CV variance was smaller for MCP sensors with a surgical glove worn underneath the data glove compared with no surgical glove.

CV for the IMU data glove show negligible changes in MCP readings when a surgical glove is worn underneath. PIP readings show small changes when using a surgical glove.

Conclusions: Inner disposable gloves can be worn when using electrogoniometric gloves for testing finger movement without loss of accuracy or any significant discomfort in patients with arthritis.

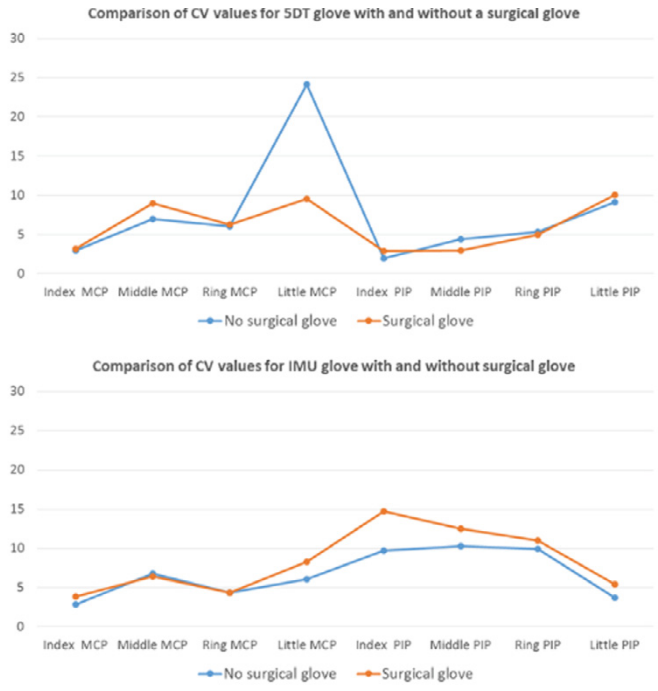

Figure 1: Comparison of Coefficient of Variation (CV) values for mean angular readings for both data gloves, with and without a surgical glove worn underneath.

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THU0672 REAL WORLD EVIDENCE COMPARING THE PATIENT REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM TO THE CDAI IN RHEUMATOID ARTHRITIS PATIENTS

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Background: Patient (Pt) reported outcomes (PROs) play a role in overall disease evaluation, therapeutic response assessment and care of rheumatoid arthritis (RA) patients (Pts). The Pt Reported Outcomes Measurement Information System (PROMIS [P]) questionnaires developed by the NIH have been validated and are a feasible assessment tool in RA (Bartlett 2015).

Objectives: AWARE (Comparative and Pragmatic Study of Golimumab Intravenous (IV) Versus Infliximab in RA) is a real-world study of golimumab IV (G-IV) vs. infliximab (IFX) in RA and will assess infusion reactions, disease activity and multiple PROs as outcomes measures.

Methods: AWARE is a prospective, noninterventional, ongoing US-based study in which 1,200 adult Pts will be enrolled on initiation of treatment with G-IV or IFX. Objectives include PRO assessments of Pt response to treatment using the PROMIS-29 Profile v2.0 (P29v2), P Pain Interference Short Form-6b (PISF) and P Fatigue Short Form-7a (FSF), 36-Item Short Form Health Survey (SF-36v2) and the Clinical Disease Activity Index (CDAI). We report an interim analysis from the first 353 Pts of baseline PROMIS questionnaire and CDAI scores, and their inter-relationships. PROMIS questionnaire results are scored on a 0 to 100 scale, normed to the US population and reported as a “T-score” (mean of 50 and standard deviation (SD) of 10). PROMIS T scores were compared across CDAI disease activity (DA) categories.

Results: Baseline mean (SD) CDAI score was 33.46 (±15.79), with 73.4% of pts with high DA (HDA), 22.1% with moderate disease activity (MDA), 3.7% with low disease activity (LDA) and 0.8% pts in remission. PROMIS scores are shown below. All P29v2 domains, PISF and FSF scores were significantly worse in pts with CDAI>22 vs. CDAI≤22 ($p<0.05$). The same was true for SF-36 domains (data not shown). PROMIS scores are shown below for all pts, and also based on CDAI DA category. PROMIS T scores across all domains (P29v2 domains, PISF and FSF) were compared to CDAI disease activity category (below). As shown, PROMIS T scores correlated with CDAI disease category, with HDA Pt T scores significantly (*, $p<0.05$) greater than those of MDA, LDA and Remission pts (excepting the Sleep Disturbance domain).

Mean PROMIS T Score of All Patients in Interim Analysis Dataset and a Comparison of T Scores of PROMIS-29 Domains, Fatigue Short Form and Pain Interference Short Form to CDAI Disease Activity Category

	All Patients (n=353)	Remission CDAI</=2.8 (n=3)	LDA 2.8<CDAI</=10 (n=13)	MDA 10<CDAI</=22 (n=78)	HDA CDAI>22 (n=259)
P29-Physical Function	37.5 ± 6.4	50.1 ± 6.07	43.5 ± 7.37	39.7 ± 6.83	36.4 ± 5.66*
P29-Anxiety	54.5 ± 10.3	44.8 ± 7.74	50.4 ± 9.12	51.6 ± 10.0	55.7 ± 10.24*
P29-Depression	52.7 ± 10.1	43.7 ± 4.62	46.2 ± 7.25	49.8 ± 10.18	54.0 ± 9.91*
P29-Fatigue	59.9 ± 9.6	41.8 ± 7.53	51.1 ± 9.57	56.9 ± 9.55	61.5 ± 9.04*
P29-Sleep Disturbance	56.0 ± 8.3	52.8 ± 14.36	52.3 ± 6.41	54.1 ± 8.48	56.8 ± 8.17
P-29 Ability to participate in Social Roles and Activities	42.3 ± 8.2	56.2 ± 9.18	49.9 ± 8.43	44.5 ± 8.84	41.2 ± 7.50*
P29-Pain Interference	64.0 ± 7.5	45.7 ± 7.1	54.3 ± 7.81	61.0 ± 8.10	65.5 ± 6.35*
Fatigue SF 7a	60.3 ± 8.3	43.0 ± 10.19	54.3 ± 7.65	57.5 ± 7.22	61.7 ± 8.02*
Pain Interference SF 6b	63.0 ± 7.7	43.5 ± 4.33	54.6 ± 9.29	59.9 ± 8.03	64.5 ± 6.62*
P29 Pain Intensity (scored 0-10 scale)	6.2 ± 2.2	2.0 ± 3.46	3.5 ± 1.71	5.4 ± 2.32	6.6 ± 1.91*

T scores > 50 indicate worsening of the domain relative to the general population, except "Physical Function" and "Ability to participate in Social Roles and Activities", where T-scores < 50 indicate worsening of these domains relative to the general population. * = p<0.05 vs respective scores in MDA, LDA and remission DA categories

Conclusions: These interim data further support the viability of using PROMIS questionnaires to evaluate RA pts, and indicate in this predominantly HDA population of RA pts correlations between PROMIS and CDAI disease activity category. Confirmation of the baseline interim analysis findings with the fully enrolled AWARE study, as well as inclusion of longitudinal and subset analyses based on disease activity levels, will further define the role of PROMIS relative to CDAI in RA patients in a real world setting.

Disclosure of Interest: J. Curtis Consultant for: Janssen, AbbVie, Roche/Genentech, BMS, UCB, Myriad, Lilly, Amgen, Pfizer, Corrona, S. Kafka Employee of: Janssen Scientific Affairs, LLC, D. Parenti Employee of: Janssen Scientific Affairs, LLC, S. Black Employee of: Janssen Scientific Affairs, LLC, S. Xu Employee of: Janssen Research & Development, LLC, Y. Wang Employee of: Janssen Research & Development, LLC, C. Bingham III Grant/research support from: Janssen, PCORI, NIH, Pfizer, Consultant for: Janssen, AbbVie, Amgen, BMS, Celgene, Genentech/Roche, Lilly, Macrogenics, Meoblast, Novartis, NovoNordisk, Pfizer, Regeneron, UCB

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THU0673 THE EUROPEAN CONSENSUS FINDING STUDY GROUP (ECFSG) HELPS CHARACTERIZING NEW TENTATIVE REFERENCE STANDARDS FOR AUTOANTIBODY MEASUREMENT

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Background: Since 1988, the European Consensus Finding Study Group on autoantibodies in rheumatic diseases (ECFSG), also known as the EULAR autoantibody study group, has been distributing sera with unspecified antibodies to European laboratories (presently n=43) for evaluation of different autoantibody measurement techniques in a clinical context. Use of reference materials helps to align test results by adopting internationally used measurement units, but reference materials are missing for many autoantibody specificities.

Objectives: Recently the scope for ECFSG was expanded to also include unbiased autoantibody characterization of serum/plasma specimens planned to constitute raw material for production of future autoantibody reference materials.

Methods: Four samples were included to be evaluated as future tentative international reference materials for four different autoantibody specificities: double stranded/native DNA (dsDNA, evaluated in 2013/14), IgG anti-b2GP1, proteinase 3 (PR3) and myeloperoxidase (MPO, evaluated in 2015/16). The samples were included "blind", and evaluated broadly for multiple autoantibody specificities by participating laboratories.

Results: All or almost all participating laboratories detected the target specificities, and all four samples showed restricted autoantibody specificities related to the target specificity. Anti-dsDNA was detected by all laboratories using *Crithidia luciliae*, ELISA/EIA, FARR assay or ALBIA and all labs reported a homogenous ANA pattern. Other specificities were restricted to histones, nucleosomes and anti-Ku. All laboratories but one detected IgG anti-b2GP1 and IgG anti-cardiolipin, mostly in high levels, in the tentative IgG anti-b2GP1 reference standard, whereas corresponding IgA and IgM antibodies were absent. All laboratories detected anti-MPO, mostly monospecific and in high levels together with P-ANCA pattern in the anti-MPO reagent. Anti-PR3 and C-ANCA pattern, mostly in high levels/titers were detected by all laboratories in the tentative anti-PR3 reagent, irrespective of method used.

Conclusions: The expanded scope of ECFSG has enabled broad characterization of new tentative autoantibody reference standards. The anti-dsDNA specimen has been processed by the National Institute for Biological Standards and Control (NIBSC) for consideration as the 2nd WHO anti-dsDNA reference standard. The other materials are basis for certified reference material for IgG anti-myeloperoxidase (ERM-DA476/IFCC), and the candidate reference materials for IgG anti-proteinase 3 (in certification) and for IgG anti-b2PG1 (in evaluation) from the Joint Research Centre.

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THU0674 ANTI-DFS70 ANTIBODY – A BIOMARKER THAT AID IN THE EXCLUSION OF ANA ASSOCIATED RHEUMATIC DISEASES

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Background: Positive ANA may lead to additional testing and potentially even inappropriate treatment in patients with rheumatic symptoms not caused by ANA associated rheumatic diseases (AARD).

Objectives: It has been shown that autoantibodies directed against lens epithelial derived growth factor (LEDGF), also named DFS70 according to the staining pattern (dense fine speckled) and molecular weight of the target antigen (70 kDa), are common among ANA positive individuals with no evidence of AARD [1,2]. The aim of our study was to evaluate if autoantibodies directed against DFS70 can be used to exclude AARD in ANA positive patients.

Methods: Anti-DFS70 antibody were determined by chemoluminescence assay (CIA) in sera of 352 apparently healthy controls (AHI), 1048 patients of an ANA positive routine cohort, 579 patients with AARD (300 SLE, 76 idiopathic inflammatory myopathies, 167 systemic sclerosis, 36 Sjögren's syndrome), 56 patients with undifferentiated connective tissue disease (UCTD), and 660 non-AARD patients (302 rheumatoid arthritis, 94 ANCA-associated vasculitis, 87 atopic rhinitis, 135 pediatric patients with celiac disease, and 42 autoimmune liver diseases).

Results: In AHI and in the non-AARD cohort, anti-DFS70 antibodies occur with a prevalence of 5.1% and 2%, respectively. Of the 1048 selected routine sera, 205 (19.6%) were positive for anti-DFS70 antibodies. Up to now, clinical reports are available for 116 of anti-DFS70 positive patients in this group. The diagnoses were widely scattered (nonspecific rheumatic symptoms, arthritis, thyreoiditis, asthma, psoriasis, tumor, infections, inflammatory bowel disease), but no definite AARD could be diagnosed. In the AARD group, only 6 of 579 patients (1.2%) were positive for anti-DFS70 antibodies, all of them also show disease specific autoantibodies (two anti-Scl70 antibody positive SSc, one anti-RNAPIII antibody positive SSc, one Ro-52 positive SSc, one anti-Mi-2 antibody positive IIM, one SLE patient with multiple autoantibodies including dsDNA antibodies). In patients with UCTD, 6 (10.7%) were anti-DFS70 antibody positive in the absence of disease specific autoantibodies. Up to now, no development of an AARD was observed in these patients.

Conclusions: Anti-DFS70 antibodies are frequently observed in sera with chromatin binding antibodies in the absence of disease specific autoantibodies. If anti-DFS70 antibodies are positive in the absence of AARD specific autoantibodies, an AARD can be excluded with high certainty.

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THU0675 DEVELOPMENT AND PSYCHOMETRIC VALIDATION OF A TOOL TO ASSESS THE FEARS OF PATIENTS WITH CHRONIC INFLAMMATORY RHEUMATIC DISEASES: THE FAIR SCALE

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Background: Patients (pts) with chronic inflammatory rheumatic diseases (CIRDs) such as rheumatoid arthritis (RA) and axial spondyloarthritis (axSpA) have fears related to their disease that can negatively impact health-related quality of life and compromise treatment adherence.

Objectives: To develop and validate a patient-reported outcome (PRO) ques-