for all patients were reviewed through June 2015. Patients with a diagnosis of PMR prior to 2000, or at another care facility, and those with an incorrectly registered PMR diagnosis code, were excluded. In a structured review of the case records, information required for classification according to the ACR/EULAR criteria, the Bird criteria, the Healey criteria, the Chuang&Hunder criteria and the Jones&Hazelman criteria was extracted. For the ACR/EULAR criteria, a modified version, in which patients who had never been tested for rheumatoid factor (RF) and anti-citrullinated peptide antibodies (ACPA) only required 2 points to be classified as having PMR, was used. Furthermore, as duration of morning stiffness (MS) was usually not recorded, criteria components for MS were considered to be fulfilled whenever MS was mentioned in the records. The reference method was an independent review, with assessment of the long term disease course and differential diagnoses, by an experienced rheumatologist with access to all electronic records.

Results: A total of 305 patients with a registered diagnosis of PMR were reviewed. Of these, 117 were excluded. Among 188 with an incident PMR diagnosis at the study sites during the study period, 49 (26 %) fulfilled the modified ACR/EULAR criteria, whereas 145 (77 %) fulfilled the Bird criteria and 93 (49 %) fulfilled the Healey criteria. Patients could not be classified according to the Chuang&Hunder or the Jones&Hazelman criteria due to missing data in most patients for several components. RF and ACPA were tested in only 42 cases (4 positive) and 29 cases (none positive), respectively. The PMR diagnosis was verified using the reference method in 113 cases (60 % of total; 68 % female, mean age at diagnosis 75 years). Among those fulfilling the modified ACR/EULAR criteria, the diagnosis was verified in 84 % of the patients. The corresponding proportion for the Bird criteria was 66 %, and for the Healey criteria 74 %.

Conclusions: In this study of patients with PMR diagnosed in PHC, the diagnosis could be verified in 60 % of the patients. This underlines the heterogeneity of PMR patients and related diagnostic procedures in PHC. A modified version of the ACR/EULAR criteria can be used to identify patients with a valid PMR diagnosis in retrospective surveys, but does not capture all PMR patients. The modified ACR/EULAR criteria appear to be more stringent than some of the older criteria sets.

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FRI0654

IS THE PATIENT-ACCEPTABLE STATUS SIMILAR ACROSS 7 DOMAINS OF HEALTH IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA)? POST-HOC ANALYSES FROM THE VALIDATION IN 549 PATIENTS OF THE RHEUMATOID ARTHRITIS IMPACT OF DISEASE (RAID) SCORE

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Background: Patient Acceptable Symptom State (PASS) is the highest acceptable level of symptoms which patients consider satisfactory. In the Rheumatoid Arthritis Impact Disease (RAID) questionnaire, seven domains of health of importance for RA patients are collected.¹. It is possible that levels judged acceptable by patients vary according to the domain of health.

Objectives: To explore the relationship between seven RA domains of health (collected in the RAID) and PASS, and to define their PASS cut-off values.

Methods: This is a *post-hoc* analysis of the cross-sectional study for RAID validation. Each of 7 domains (table 1) was evaluated through a Numeric Rating Scale from 0 (best) to 10 (worst). PASS was calculated using the anchored method based on patients' perspective. Disease activity was assessed based on the DAS28–3 values (joint counts and ESR). Comparison of patients in PASS or not was assessed through Mann-Whitney or Chi-square test, as adequate. Variables with $p < 0.05$ were included in multivariate logistic regression (Forward Conditional) analysis. The thresholds of PASS for each domain was calculated using the receiver-operating characteristic (ROC) curve and the optimal cut-off was determined through Youden Index. 75th percentile analyses were also performed (not shown).

Results: 549 patients [78% female, mean age 56.7 years, mean disease duration 12.3 years, mean (SD) DAS 28–3 2.7(1.2)] were analysed. The majority of patients (60.7%) considered themselves to be in PASS. Disease activity (DAS 28–3 mean 2.3 vs 3.4, $p < 0.01$) and all seven domains of health were significantly lower in patients in PASS versus not in PASS ($p < 0.001$). In multivariate analyses, lower disease activity (OR 0.72; 95%IC 0.56–0.92), lower pain (OR 0.75; 95%

IC:0.65–0.86) and better physical well-being (OR 0.74 95%; IC:0.65–0.85) were associated with being in PASS.

The cut-off for PASS was ≤ 4.2 for the total RAID score but varied across the seven domains (table 1), with Pain (≤ 5) and Fatigue (≤ 5) having the highest acceptability cut-offs. Sleep Disturbance and Coping were the domains with lowest thresholds compatible with PASS (≤ 3).

Table 1 Thresholds for Acceptable Status for each RAID domain, AUC: Area Under the Curve, and sensitivity and specificity versus PASS

Domain	Cut-off	AUC	Sensitivity (%)	Specificity (%)
Pain	≤ 5	0.84	80.5	72.9
Function	≤ 4	0.82	69.7	80.8
Fatigue	≤ 5	0.75	74.9	62.2
Sleep	≤ 3	0.70	64.2	67.4
Emotional Well-Being	≤ 4	0.76	75.0	64.5
Physical Well Being	≤ 4	0.81	69.3	77.1
Coping	≤ 3	0.79	65.5	77.1

Conclusions: Pain and physical well-being appeared as major drivers of PASS. The cut-offs defining PASS were not the same for all RAID domains, indicating that being in PASS doesn't mean the same acceptable severity for all domains of health. This observation suggests that individualised management, for each domain, should be considered.

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FRI0655

TITLE: THE CONSISTENCY OF OUTCOMES REPORTED IN TRIALS OF SYSTEMIC SCLEROSIS. IMPROVING OVER TIME?

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Background: Standardisation of outcome domains and measures in trials in rheumatology has generally improved the consistency and relevance of outcomes reported in rheumatic conditions over the last two decades. The Outcome Measures in Rheumatology (OMERACT) 'core response set' for trials in Systemic Sclerosis (SSc) was developed in 2008 and comprises 11 domains and 31 measures¹.

Objectives: We aimed to assess the scope, and consistency of outcomes reported in trials of SSc, and the uptake of this core response set.

Methods: MEDLINE, Cochrane CENTRAL, Embase and clinicaltrials.gov were searched to identify randomised clinical trials published between 2000 and June 2016 in adults with SSc. Outcomes and measures were recorded for each trial and classified into domains. The scope and consistency of domains were compared between those trials published from 2000 to 2010 and 2011 to mid-2016 to determine whether has been uptake of the core domain and measurement set reported. A two-year lag between publication of the core set in 2008 and start of the second-time period was set to allow for core response set uptake.

Results: Overall 114 trials (4860 patients, median sample size of 33) were identified. The majority of trials were interventions for immunotherapeutic agents or vasodilators and included a total of 2736 measures (of 78 domains), with a mean of 24 measures per trial. The proportion of trials reporting any outcome from the each domain is listed: (% of 2000–2010 trials, % of 2011–2016 trials, change in %): health-related quality of life and function (42.6, 56.5, +13.9); skin (39.7, 47.8, +8.1); pulmonary (33.8, 43.5, +9.7); global health (14.7, 21.7, +7.0); gastrointestinal (4.4, 10.9, +6.5); ; cardiac (13.2, 15.2, +2); biomarkers of ESR/CRP (7.4, 8.7, +1.3%) musculoskeletal (5.9, 6.5, +0.6); Raynaud's phenomenon (20.6, 19.6, -1.0) renal (14.7, 10.9, -3.8); digital ulcers (23.5, 19.6, -3.9%). Six measures had a greater than 5% increase in reporting frequency across trial periods: HAQ-DI (from 38.2% to 47.8%), SF-36 (from 17.6% to 28.3%), Modified Rodnan Skin