Abstract 460 Figure 1

disease duration (SD) 9.3 years (8.1). A total of 195 flares occurred in 76 patients over 781 monthly assessments, giving a flare rate of 0.25/month. There were 37 severe flares (22 patients), 32 moderate flares (19 patients) and 126 mild flares (67 patients) [Table 1]. The median time to any “A” or “B” flare was 4 months (95% CI 2.7 to 5.3 months). Figure 1 shows the time to the first mild/moderate/severe flare (Curve 1), moderate/severe flare (Curve 2) and severe flare (Curve 3). Table 2 shows that severe and moderate flares tend to be in the system/s affected at baseline whereas mild flares are more likely to affect any system.

Conclusions This real world cohort will share similarities with populations recruited to clinical studies so these results may inform future trial design.

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ASSESSING THE CONTENT VALIDITY OF THE SF-36, THE SKINDEX-29+3 PATIENT REPORTED OUTCOMES (PRO) INSTRUMENTS, AND PAIN, FATIGUE IN PATIENTS WITH CUTANEOUS LUPUS ERYTHEMATOSUS (CLE)

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Background and aims Patients with CLE may experience symptoms, which can negatively impact their quality of life. The objectives of this study were as follows: 1) to investigate patient experiences associated with CLE, 2) to investigate the impact of living with CLE on patients’ lives, 3) to evaluate the content validity of the 36-item Short Form Health Survey (SF-36) and the Skindex-29+3 PRO instruments in the CLE population, and 4) to evaluate the appropriateness of a shorter recall period of 1 week instead of 4 weeks for the Skindex-29+3.

Methods This cross-sectional qualitative study utilised a combined concept elicitation (CE) and cognitive interview (CI) method. Study participants were recruited across three US clinical sites and interviewed one-on-one during a 90 min in-person interview. Interviews followed a semi-structured interview guide that elicited patient experiences with CLE and its impact on patients’ lives, followed by CI that assessed patients’ understanding and interpretation of each instrument.

Results Patients found these instruments to be readily understandable, interpreting items correctly and with minimal difficulty. Patients reported a one-week recall period for the Skindex-29+3 to be meaningful and easy to use, although many stated that their symptoms and experiences were felt over a longer period of time.

Abstracts

Abstract 460 Table 2 BILAG2004 index disease activity system affected at baseline and at time of flare and concordance between the two by severity of flare (n_{pat} = number of patients, n_{flare} = number of flare, n_{system} = number of times system affected with flares, % = percentage of total number of times systems affected).

BILAG2004 Index	At Baseline (%) $n_{\text{pat}} = 100$ $n_{\text{flare}} = 100$ $n_{\text{system}} = 170$	Severe Flare (system with "A" score) (%) $n_{\text{pat}} = 22$ $n_{\text{flare}} = 37$ $n_{\text{system}} = 38$	Moderate Flare (%) $n_{\text{pat}} = 19$ $n_{\text{flare}} = 32$ $n_{\text{system}} = 75$	Mild Flare (%) $n_{\text{pat}} = 67$ $n_{\text{flares}} = 126$ $n_{\text{system}} = 126$	No flares (Baseline) (%) $n_{\text{pat}} = 24$ $n_{\text{flare}} = 0$ $n_{\text{system}} = 36$
Systems affected					
Constitutional	13 (7.7)	2 (5.3)	2 (2.7)	2 (1.6)	4 (11.1)
Mucocutaneous	37 (21.8)	15 (39.5)	19 (25.3)	42 (33.3)	8 (22.2)
Neurological	4 (2.4)	2 (5.3)	7 (9.3)	8 (6.3)	0
Musculoskeletal	67 (39.4)	15 (39.5)	21 (28)	41 (32.5)	15 (42.3)
Cardiorespiratory	23 (13.5)	0	12 (16)	14 (11.1)	5 (13.9)
Gastrointestinal	4 (2.4)	0	5 (6.7)	1 (0.8)	0
Ophthalmic	2 (1.2)	2 (5.3)	0	0	0
Renal	20 (11.8)	2 (5.3)	9 (12)	18 (14.3)	4 (11.1)
Haematology	0	0	0	0	0
Concordance with baseline system/s affected at first flare per patient (% of patients) n/a = not applicable					
Complete concordance		19 (86.4)	9 (47.4)	44 (65.7)	
Partial concordance		n/a	9 (47.4)	n/a	
Complete discordance		3 (13.6)	1 (5.3)	23 (34.3)	

Abstract 461 Table 1 Sociodemographic characteristics.

Patient Characteristic	Distribution (N=15)
Mean age	52.4
Sex	73% female
Race/Ethnicity	53.3% White Caucasian 40% African-American 6.7% Hispanic
Mean disease activity reported by clinician (0=inactive disease, 1=mild, 2=moderate, 3=severe disease activity)	1.46

Conclusions: The majority of instruments' items were confirmed to be meaningful, interpretable, and appropriate for use in the CLE patient population. The results of the interviews support the content validity of the SF-36 and Skindex-29+3 in the CLE patient population.

Abstract 461 Table 2 Most commonly reported symptoms.

Symptom	Distribution (N=15)
Tiredness	15 (100% of patients)
General pain	13 (87%)
Rash	13 (87%)
Joint pain	10 (67%)

Abstract 461 Table 3 Most commonly reported symptom impacts.

Impact	Distribution (N=15)
Physical functioning	13 (87%)
Social functioning	9 (60%)
Emotional functioning	9 (60%)
Work/School	8 (53%)