World Disease Specific Programme (US and Europe) (205086). Latent class modeling based on current organ involvement was used to generate clusters of patients with similar manifestations; characteristics of each cluster were compared using the chi-square test for categorical variables and Kruskal-Wallis test for ordered/numeric outcomes.

Results Overall, 1376 patients (n=1196 [87.0%] female; mean [standard deviation (SD)]) age, 42.1 [13.6] years) were included in the analysis. Four patient clusters were generated: Cluster 1 (n=250, 18.2%), lowest overall organ burden (predominantly mucocutaneous); Cluster 2 (n=670, 48.7%), joint and skin SLE (predominantly mucocutaneous and musculoskeletal) with limited renal/hematologic involvement; Cluster 3 (n=150, 10.9%), highest frequency of renal/hematologic involvement; Cluster 4 (n=306, 22.2%), highest frequency of mucocutaneous, musculoskeletal, constitutional, cardiorespiratory and neuropsychiatric involvement, but without renal involvement. Key results are summarized in the table 1. Significant between-cluster differences were observed for disease severity (p<0.0001; highest: Cluster 3); number of affected organ systems (p<0.0001; highest: Clusters 3 and 4); number of flares in prior 12 months (p<0.0001; highest: Clusters 3 and 4); disease progression (p<0.0001; most compromised: Cluster 3); time since diagnosis (p<0.001; longest: Cluster 3); and ethnicity (p<0.01; black race most prevalent: Cluster 3). Overall, the most commonly experienced symptoms were pain/inflammation and skin symptoms (p<0.0001; highest: Cluster 4). Frequency of organ involvement increased over time in Clusters 3 and 4 but decreased in Cluster 1. Statistically significant differences were observed between clusters in the number of previous treatments and treatment classes (both p<0.01). Activity impairment generally increased, while fatigue severity worsened, across the clusters (both <0.0001).

Conclusions This analysis provides important insights on potential clinically meaningful subsets of SLE (per organ system involvement) using real-world evidence. The highest disease burden was observed in Clusters 3 and 4, confirming the extensive impact of SLE irrespective of renal involvement. Limitations included the absence of serological findings or disease activity indices for cluster formation or comparison.

Abstract 50 Table 1 Concepts discussed within the CE segment of the interview

Concepts relating to SLE, n (%)*	Patients (n=15)
Impact of fatigue on reported functions	
Emotional Functioning	10 (66.7)
Physical Functioning	5 (33.3)
Social Functioning	6 (40.0)
Activities of Daily Living	4 (26.7)
Role Functioning	4 (26.7)
Most commonly reported symptoms	
Cognitive functioning	15 (100.0)
Fatigue	15 (100.0)
Pain	15 (100.0)
Sleep disturbance	15 (100.0)
Weakness	12 (80.0)
Nervous, brain	9 (60.0)
Skin	9 (60.0)
Arthritis	6 (40.0)
Hair loss	5 (33.3)
Kidney	5 (33.3)
Light-headedness	5 (33.3)
Swelling	5 (33.3)
Ulcers	5 (33.3)
Vascular	5 (33.3)
Number of patients with symptoms reported to vary in intensity over time	9 (60.0)
Triggers reported to intensify symptoms (any)	14 (93.3)
Exposure to sun/photosensitivity	12 (80.0)
Physical exertion	10 (66.7)
Stress	5 (33.3)
Cold weather	3 (20.0)
Diet	2 (13.3)
Stopping medication	2 (13.3)
Symptoms reported as the most bothersome	
Fatigue	11 (73.3)
Pain	3 (20.0)
Difficulty concentrating	1 (6.7)
Hair loss	1 (6.7)
Insomnia	1 (6.7)
Lupus nephritis/inflammation of the kidney	1 (6.7)
Raynaud's phenomenon	1 (6.7)

CE, concept elicitation; SLE, systemic lupus erythematosus. *Percentages in each category may not total 100% because participants may have reported more than one symptom, trigger, or impact.

| 50 | PATIENT INSIGHTS OF FATIGUE IN SYSTEMIC LUPUS ERYTHEMATOSUS AND CONTENT VALIDATION OF THE FACIT-FATIGUE |

[1]Josephine Park*, [2]Kimberly Raymond, [2]Michelle White, [1]Ashish Joshi. [1]GSK, Value Evidence and Outcomes; [2]Optum

Background Fatigue is a predominant symptom experienced by patients with systemic lupus erythematosus (SLE) and is known to have a significant burden on daily life. To capture the impact of fatigue on patients with SLE accurately and effectively, a validated fatigue measure must be utilized. This study (GSK Study 209226) evaluated the content validity of the Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue instrument to investigate whether this instrument is a valid and appropriate measure of fatigue within this population and to understand SLE related fatigue better.

Methods Fifteen 90 min qualitative interviews were conducted by telephone in July 2018 using concept elicitation (CE) and cognitive debriefing techniques. Participants were asked to share their experiences of SLE symptoms, focusing on fatigue and its impact on their daily life. Participants were then asked to evaluate how well they interpreted and understood the questions and response options of the FACIT-Fatigue instrument, along with the appropriateness and relevance of the items, response scales and recall periods. Patients were eligible to participate if they were 18 years of age, had a self reported doctor diagnosis of SLE with persistent symptoms for 6 months or 1 SLE flare in the previous 12 months despite treatment with steroids/

immunosuppressants. Participants were positive for antinuclear antibody or antidouble-stranded deoxyribonucleic acid and spoke fluent English.

Results The sample (female, n=13/15) was diverse by age (mean [standard deviation] age 52.1 [13.1] years), race and ethnicity, severity, and time since diagnosis. Results of the CE segment of the interview are displayed in the table. Eleven participants (73.3%) reported fatigue as their most bothersome symptom. Significant impacts of fatigue were described in relation to emotional (n=10), social (n=6), and physical (n=5) functions, as well as role difficulties (n=4) and struggles with activities of daily living (n=4). Qualitative analyses revealed that all FACIT Fatigue items map directly onto concepts spontaneously mentioned by participants during the interviews. All participants reported that the FACIT Fatigue items were easily understood, relevant, appropriate, and concise, and captured the most important concepts related to fatigue in SLE.

Conclusions The interviews demonstrated fatigue to be a central concern to patients with SLE and supported the content validity of the FACIT-Fatigue instrument as an appropriate and interpretable assessment of fatigue for this population. This study provides valuable insights into the experiences of patients with SLE and, specifically, the impact of fatigue on these patients.

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51 BIRTHS TO WOMEN WITH SYSTEMIC LUPUS ERYTHEMATOSUS CAN BE IDENTIFIED ACCURATELY IN THE ELECTRONIC HEALTH RECORD

[1]Ashley Blaske, [2]M Amanda, [3]Jim Oates, [1]Leslie Crofford, [2]Megan EB Clowse, [1]April Barnado. [1]Vanderbilt University Medical Center; [2]Duke University; [3]Division of Rheumatology and Immunology, Medical University of South Carolina

Background Studying births to women with systemic lupus erythematosus (SLE) is difficult given its rarity and the challenges of prospective cohort studies. While the electronic

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Abstract 51 Table 1

Algorithm	PPV training set[a]	PPV validation set[b]	Sensitivity training set	Sensitivity validation set	F-Score[c] training set	F-Score validation set
Any Clinician Coded						
ICD-9 code only						
≥1 count of the ICD-9 code	57%	66%	100%	88%	73%	75%
≥4 counts	77%	80%	87%	69%	82%	74%
ICD-10 codes only						
≥1 count of the ICD-10 code	77%	67%	95%	98%	85%	80%
≥4 counts	94%	73%	71%	83%	81%	78%
ICD-9 or ICD-10 code counts						
≥1 ICD-9 or ICD-10 code	56%	65%	100%	93%	72%	77%
≥4 ICD-9 or ICD-10 codes	81%	76%	95%	75%	87%	75%
ICD-9 or ICD-10 code counts AND antimalarials ever used						
≥1 ICD-9 or ICD-10 code	68%	72%	85%	41%	76%	52%
≥4 ICD-9 or ICD-10 codes	83%	77%	83%	38%	83%	51%
ICD-9 or ICD-10 code AND labs ever checked						
≥1 count	62%	72%	95%	86%	75%	78%
≥4 counts	84%	85%	93%	54%	**88%**	66%
ICD-9 or ICD-10 code AND ANA+[c]						
≥1 count	64%	70%	76%	63%	69%	66%
≥4 counts	79%	77%	76%	52%	77%	62%
Rheumatology Coded						
ICD-9 code only						
≥1 ICD-9 code	78%	86%	86%	73%	82%	79%
≥4 ICD-9 codes	88%	94%	70%	48%	78%	64%
ICD-10 codes only						
≥1 ICD-10 code	70%	82%	70%	83%	70%	**82%**
≥4 ICD-10 codes	88%	92%	45%	71%	60%	80%
ICD-9 or ICD-10 codes						
≥1 ICD-9 or 10 code	78%	85%	76%	80%	77%	**82%**
≥4 ICD-9 or 10 codes	85%	93%	71%	55%	77%	69%
ICD-9 code: 710.0. ICD-10 codes: M32.1,* M32.8, M32.9						

[a]The training set consisted of 100 subjects from the Vanderbilt EHR.
[b]The validation set consisted of 545 subjects from the Duke Autoimmunity in Pregnancy Registry and Duke EHR
[c]F-score: measure of performance of an algorithm, harmonic mean of PPV and sensitivity calculated as 2 x [(PPV x Sensitivity)/(PPV +Sensitivity)]
[d]ANA positive ≥1:160.