

# Patient Characteristics and Current Management of Systemic Lupus Erythematosus Patients in a Large, Representative US-based Real-World Registry Cohort

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## Background

- Systemic lupus erythematosus (SLE) is a heterogeneous, multifactorial disease with a debilitating and highly variable clinical course.
- Real world data are critical to better understanding these patients and their unmet clinical needs, particularly as inclusion and exclusion criteria for clinical studies are by design highly restrictive and typically not representative of the overall SLE population.
- Disease activity scores such as the self-reported Multidimensional Health Assessment Questionnaire (MDHAQ) and the Health Assessment Questionnaire (HAQ) collect information on disability not captured by more commonly used clinical assessments.
- Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) scores are not widely used in standard clinical practice but may be useful for assessing changes in disease activity.

## Objective

- The assess clinical, symptomatic, and disease activity information in SLE patients.

## Methods

- The OM1 SLE Registry (OM1, Boston), an ongoing, continually enrolling, representative sample of patients with SLE in the US who are followed prospectively, was used to assess clinical, symptomatic, and disease activity information. The combined electronic medical record data (EMR) and administrative claims dataset provided additional insights into the complete patient journey, including specialty data from rheumatologists, with deep clinical data within both structured and unstructured fields.
- ICD and SNOMED diagnosis codes were used to identify patients with key clinical manifestations. NDC and CPT procedure coded prescription fills and medication orders were used to identify disease-modifying therapies (DMTs) and other treatments for lupus.
- MDHAQ, HAQ, and SLEDAI scores were obtained from structured EMR data documented during clinical care.
- SLEDAI scores were categorized by disease severity (no disease activity [0], mild [1-5], moderate [6-10], high [11-19], very high [ $\geq 20$ ]), and transitions between first and last observed categories were described.

Abbreviations: ICD, International Statistical Classification of Diseases and Related Health Problems; SNOMED, Systematized Nomenclature of Medicine; NDC, National Drug Code; CPT, Current Procedural Terminology

## Results

- The cohort included 36,603 SLE patients with deep clinical rheumatology data ranging from January 2013 to May 2019.
- The mean age was 51.5 years [standard deviation (SD) 15.0], and consistent with the epidemiology of lupus, 92% of patients were female.
- Nearly 20% had evidence of lupus nephritis or proteinuria, while 2% had lupus endocarditis or pericarditis.
- Five percent of patients were treated with the DMT, belimumab (Benlysta®), and 74% were treated with antimalarial medications.
- Among the 10,597 patients with at least one MDHAQ score, the average number of scores per patient was 4.38 (SD: 4.78). The distribution of first observed MDHAQ score is presented in **Table 1**.
- Among the 1,946 patients with at least one HAQ score, the mean number of scores per patient was 4.56 (SD: 5.82). The distribution of first observed HAQ score is presented in **Table 1**.
- SLEDAI scores were reported for 1,451 patients, and approximately 20% showed high or very high disease activity on their first reported score. The distribution of first observed SLEDAI score is presented in **Table 2**.

**Table 1: Distribution of First Observed MDHAQ and HAQ Scores**

	MDHAQ		HAQ		
	N	%	N	%	
0 to <1	3,615	34%	0 to <1	1,119	58%
1 to <3	3,245	31%	1 to <2	624	32%
3 to <5	2,303	22%	2 to <3	193	10%
$\geq 5$	1,434	14%	3	10	1%

**Table 2: Distribution of First Observed SLEDAI Score**

SLEDAI		
	N	%
No disease activity (0)	334	23%
Mild (1-5)	425	29%
Moderate (6-10)	407	28%
High (11-19)	179	12%
Very high ( $\geq 20$ )	106	17%

## Conclusions

- Use of a representative, real world cohort of SLE patients followed by rheumatologists provides unique information on treatment patterns and outcomes.
- Disease activity scores may be useful for identifying patients for trials, but are not routinely collected in clinical practice. The MDHAQ may be easier to collect than the HAQ as it is self-administered and more commonly used in clinical practice.
- Treatment options are currently limited to a single DMT, and more typically, a combination of off-label immunosuppressants and steroids, demonstrating an unmet clinical need for patients with this debilitating condition.