Abstract 1118 Table 1 Estimated Number of New Persons Diagnosed with Systemic Lupus Erythematosus in the United States in 2018

	FEMALE				
Race/Ethnicity (Number of sites in analysis)	**SLE Incidence** [a] per 100,000 (95% CI)		**Population Denominator**	**Estimated # SLE Cases in United States** (95% CI)	
Race					
Black (4)	15.9	(12.5, 20.3)	24,880,722	3,956	(3,110, 5051)
White (4)	5.7	(4.9, 6.7)	130,137,989	7,418	(6,377, 8719)
Asian/PI (2)	7.6	(5.5, 10.4)	12,544,896	953	(6,90, 1305)
AI/AN (1)	10.4	(6.6, 14.6)	2,238,966	233	(148, 327)
Total [b]	**8.7**	**(8.1,9.4)**	**169,802,573**	**12,560**	**(10,325, 15,402)**
Ethnicity					
Hispanic [c] (2)	6.8	(6.2, 7.6)	30,689,083	2,087	(1,903, 2332)
	MALE				
	Incidence [a] per 100,000 (95% CI)		**Population Denominator**	**Estimated # SLE Cases in United States** (95% CI)	
Race					
Black (4)	2.4	(1.8, 3.2)	22,961,129	551	(413, 735)
White (4)	0.8	(0.6, 1.1)	127,942,583	1,024	(768, 1,407)
Asian/PI (2)	0.4	(0.2, 0.6)	11,660,533	47	(23, 70)
AI/AN (1)	3.8	(1.6, 7.8)	2,134,870	81	(34, 167)
Total [b]	**1.2**	**(0.9, 1.6)**	**164,699,115**	**1,703**	**(1,238, 2,379)**
Ethnicity					
Hispanic [c] (2)	0.9	(0.4, 1.9)	31,281,605	282	(125, 594)

Systemic lupus erythematosus cases were defined according to the 1997 revised American College of Rheumatology criteria.
[a]Estimates for Blacks and Whites are based on pooled estimates from the four state-based registries; Asian/Pacific Islanders (Asian/PI) and Hispanics are based on pooled estimates from California and New York; American Indian/Alaska Native (AI/AN) estimates are based on the Indian Health Service Registry.
[b]The pooled 'total' incidence estimate includes Black, White and Asian/Pacific Islanders (Asian/PI). Since the American Indian/Alaska Native (AI/AN) incidence was based on one registry and was significantly higher, it was not included in the pooled incidence per 100,000.
[c]Hispanic ethnicity is not mutually exclusive from the race categories, i.e., all Hispanic persons are included in one of the race categories. Thus, the pooled estimates do not incorporate the Hispanic rates since that would lead to duplicate counting. Estimates for Hispanics are based on pooled estimates from California and New York.

Conclusion A coordinated network of population-based SLE registries provided more accurate estimates of the incidence of SLE and the numbers of new individuals affected with SLE in the U.S. in 2018.

1119 RECRUITMENT AND ENROLLMENT INTO A DIRECT-TO-FAMILY PEDIATRIC LUPUS TRIAL

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Background A direct-to-family or virtual approach can improve participant recruitment, retention, and diversity, and improve efficiency of clinical trials. Pediatrics and rare disease may especially benefit from this approach. Recruitment and enrollment of direct-to-family trials in pediatric lupus has not been described. We hypothesize that engaging patients and leveraging a disease registry will facilitate recruitment and enrollment into a direct-to-family pediatric lupus trial (NCT: 04358302).
Objective Evaluate the feasibility of enrolling and recruiting participants into a nationwide, novel direct-to-family pediatric lupus trial
Methods Investigators and study leaders collaborated with patients and advocacy groups, key stakeholders, and a disease registry (Childhood Arthritis and Rheumatology Research Alliance, CARRA Registry) to design a direct-to-family pediatric lupus trial. Participants across the country were identified through the CARRA Registry. Recruitment and informed consent/assent were conducted remotely by a single site (Duke Clinical Research Institute, DCRI).
Results 191 potentially eligible participants were identified through the CARRA Registry. Of the 84 participants who participated in a live discussion, 44 (52%) scheduled a consenting call. The original enrollment goal of 20 participants was met in 10 days. Enrollment was increased to 26, and an additional 18 participants were added to a back-up list due to high interest.
Conclusions Using a single site to recruit and enroll participants into a nationwide direct-to-family pediatric lupus trial was highly feasible, quick, and effective. Recruiting participants from a disease registry and engaging patient advocacy groups were key to successful enrollment.

1120 DETERMINATION OF THE MINIMAL CLINICALLY IMPORTANT DIFFERENCE (MCID) OF THE PHYSICIAN GLOBAL ASSESSMENT (PGA) IN SLE

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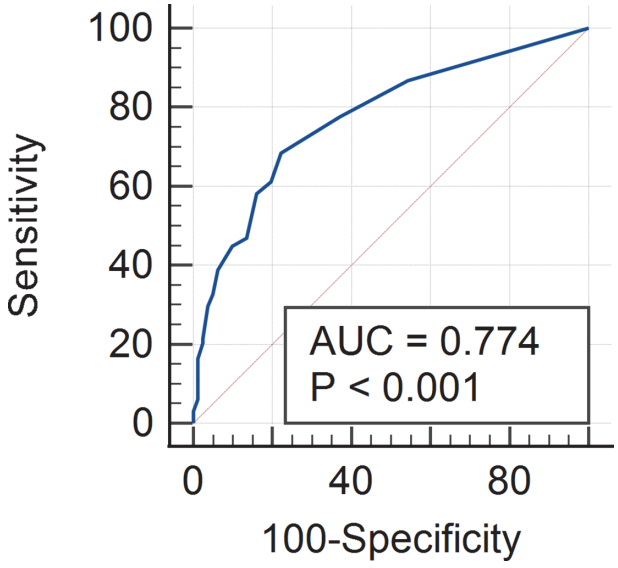
Introduction The PGA is a SLE outcome measurement reflecting the physician's assessment of a patient's disease activity. It is considered a 'gold standard' and contributes to responder indices for clinical trials, as well as to definitions of the low lupus disease activity state (LLDAS) and remission. Although a few studies have evaluated its sensitivity to change, no studies have assessed its minimal clinically important difference (MCID). Our objective was to determine the MCID of the PGA using prospective data collected in a single center.
Methods PGAs were scored prospectively by 3 physicians on consecutive patient visits; the difference between a visit PGA and the previous visit's PGA was the ΔPGA. A disease flare visit was defined as a visit in which therapy was increased (initiation or increase of corticosteroid dose and/or DMARD or biologic agent). We constructed a receiver operating characteristics (ROC) curve to visualize the performance of the ΔPGA for predicting flare and determined the MCID of the PGA for flare using an anchored approach by calculating Youden's index for the ΔPGA in 0.1 increments.
Results Data from 129 patient visits with ΔPGA and therapeutic decisions (therapy increase/flare or therapy decreased or no change/no flare) were available. The baseline PGA was between 0- 0.9 in 79 visits, 1.0-1.9 in 38 visits and between 2.0-3 in 12 visits. Flare occurred in 85 visits while no flare occurred in 44 visits with 43 (50.6%) of flares occurring with a baseline PGA between 0-0.9, 30 (35.3%) with a baseline PGA between 1-1.9 and 12 (14.1%) flares with a baseline



Abstract 1120 Figure 1 Receiver Operating Characteristic (ROC) curve of ΔPGA for predicting flare. AUC = Area under the curve.

between 2-3. The ROC curve for the performance of ΔPGA in predicting flare is shown in figure 1. The area under the curve was 0.774 (SE .034), p<0.001. A ΔPGA of 0.3 is associated with the highest Youden's index.

Conclusion Preliminary results from this small observational study suggest that the MCID for the PGA is 0.3. Larger studies evaluating the ΔPGA and flare, scored by multiple physicians are necessary.

1121 EVALUATION OF COMORBIDITIES AND DAMAGE IN CANADIAN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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Background Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease with a wide array of clinical manifestations, treated with corticosteroids and long term immunosuppressants to reduce the disease activity and damage. Our objectives were to examine a Canadian cohort of SLE patients in comparison to the general Canadian population to examine potential risk factors for comorbidities and disease damage in SLE patients. We hypothesize that SLE patients accumulate more damage and comorbidities with greater disease activity and corticosteroid exposure over time compared to the general population.

Methods We explored the Canadian Network for Improved Outcomes in SLE (CaNIOS) registry, a multi-centred cohort of Canadian SLE patients, to identify prevalence of damage using the SLICC SLE Damage Index (SDI) and comorbidity using the Charlson Comorbidity Index (CCI). We also performed an age-matched data analysis to compare the comorbidities prevalence between the CaNIOS registry and the general Canadian population (Canadian Community Health Survey). Exploratory analysis was done using descriptive statistics. Univariable analysis was performed to identify potential predictors of comorbidities and damage in the CaNIOS SLE population at baseline. Variables that were significant at the univariable level were included in Generalized Linear Model (GLM).

Results 603 SLE patients from the CaNIOS registry were included, mean age 50.9 years (SD=14.6), average disease duration 14.2 years (SD=11.9), 91% being female. Mean SLE disease activity score (SLEDAI) was 3.1 (SD 3.5) and mean ACR classification criteria 5.3 (1.5). Mean CCI was 1.33 (SD=0.69), and mean SDI was 1.34 (SD=2.04). The most common comorbidities in CaNIOS patients were cerebrovascular disease (6.5%), followed by solid tumours (5.8%). Compared to their age-matched general population counterparts, SLE patients had higher rates of cancer (7.8% vs 2%) and cerebrovascular disease (6.5% vs 1.8%) (p<0.0001). Multivariable GLM showed age to be a significant predictor for increased comorbidities (p<0.05). Baseline risk factors associated with increased damage (SDI) were age, longer disease duration, higher ACR scores, current smoking and prednisone use within the last year (p<0.05). Female gender (p<0.0160), a recent onset of disease (<12 months) (p<0.0001) and intravenous steroid use (p<0.0286) were found to be associated with less disease damage.

Conclusions Canadian lupus patients have a greater burden of certain comorbidities compared to the general population. Identifying the risk factors associated with comorbidities and greater disease damage is a very important step in treating those patients.

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1122 VALIDATION OF A NOVEL LUPUS MULTIVARIABLE OUTCOME SCORE AS AN OUTCOME MEASURE FOR SYSTEMTIC LUPUS ERYTHEMATOSUS TRIALS

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Background Development of effective new Systemic Lupus Erythematosus (SLE) treatments requires a validated responder index responsive to clinically meaningful change and relevant to clinical practice. To address this challenge, we have recently developed a new Lupus Multivariable Outcome Score (LuMOS) to optimize discrimination between outcomes of actively treated patients *versus* those on placebo.[1] We now report on external validation of LuMOS in two independent SLE clinical trials.

Methods Validation was carried out in the Illuminate trials that evaluated tabalumab (TB) in SLE. All participants in both Illuminate 1 and 2 trials met the ACR classification criteria for SLE and all were included in our analyses. To adapt LuMOS for use with laboratory results assessed on different platforms than used in the trials of belimumab employed to generate the original LuMOS outcome score.[1] we calculated a standardized score using z-score transformations. For validation, in each of the Illuminate trials, we calculated LuMOS scores at week 52 for all participants receiving either placebo or one of 2 dosage regimens of TB. Cohen D Effect Size (ES), with 95% confidence intervals (CI), assessed the ability of LuMOS to discriminate between outcomes in active