609 DEMOGRAPHIC AND CLINICAL FACTORS THAT CONTRIBUTE TO CLINICAL STUDY ENROLLMENT

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Background/purpose Participation in clinical trials is part of the treatment algorithm for many patients with chronic diseases. However, patients with systemic lupus erythematosus (SLE), especially those of African-American and Hispanic descent have been reluctant to participate in clinical trials. Qualitative research identified patient, provider, community, and study design factors as the main reasons for this hesitancy. Concerted efforts to increase awareness and education about SLE clinical trials are underway. We evaluated factors associated with challenges to clinical trial enrollment in the Columbia University Lupus Cohort (CU).

Methods A six-session educational intervention modeled after the Lupus Research Alliance Patient Advocates for Lupus Studies (PALS) program and sponsored by the Department of Health and Human Services – Office of Minority Health is currently underway. The target enrollment is 200 patients from 3 New York City cohorts that include large numbers of disparate patients. SLE patients from CU, mostly from the Washington Heights area of New York City, were invited to participate during routine clinic visits. The patients were appraised of the study in detail and their decision to participate or refuse was recorded. Socio-demographics and disease characteristics were collected. Data from recent therapeutic clinical trial participants was included for comparison. One-way ANOVA was used to detect differences among the 3 groups: refused participation, enrolled in the study, and clinical trial participants.

Results Of the 45 patients asked to participate, 30 (66.7%) agreed, while 15 (33.3%) refused. Additionally, 25 clinical trial participants were included. Clinical trial participants were more likely to have arthritis (96% vs 67% vs 83%, p=0.047), mucocutaneous manifestations (88% vs 73% vs 73%, p=NS) and be on steroids (56% vs 7% vs 17%, p=0.001) as required for inclusion in clinical trials. Participants enrolled in the educational sessions, demonstrating willingness to engage in clinical trial education, were more likely to have been admitted during the past year (1.63 vs 1.13 vs 0.52, p=0.009), have higher zip-code median income (55K vs 56K vs 77, p=0.03), have less rheumatology office visits (3.13 vs 3.20 vs 4.76 p=0.06) and have co-morbid fibromyalgia (13% vs 0% vs 0%, p=0.06). While there were more Blacks and Hispanic patients in the education group these differences did not reach statistical significance. Detailed data is summarized in table 1. The major reasons for refusal to participate in the program were lack of interest in clinical trial education (7, 47%), time constraints (5, 33%), and negative prior experiences relating to clinical trials (3, 20%).

Conclusion These data suggest that people's intention to participate in clinical studies is influenced by disease severity (admissions and office visits), patient factors (income and co-morbid fibromyalgia) and study design (arthritis, steroid use). It is difficult to ascertain if racial and ethnic factors affect the current study enrollment. More data is needed to confirm the role of these factors and additional qualitative data will help identify factors that mediate a patient's decision at the individual level.

Abstract 609 Table 1 Demographic and Clinical Factors Among SLE Patients (n=70)

	Enrolled in the study (n=30)	Refused (n=15)	Clinical Trial Participants (n=25)	p-value
Demographics				
Age (mean ± SD)	41.87 ± 13.14	38.87 ± 13.85	37.84 ± 12.46	0.502
Female (n,%)	29, 97%	12, 80%	23, 92%	0.174
Black (n,%)	12, 40%	4, 15%	5, 20%	0.305
Ethnic Hispanic (n,%)	14, 57%	5, 33%	7, 28%	0.078
Income, $ (mean ± SD)	55711 ± 22853	56037 ± 28671	77378 ± 42968	**0.035**
Years Since SLE Diagnosis (mean ± SD)	10.04 ± 10.71	8.60 ± 6.52	12.04 ± 7.48	0.243
SLE Organ Involvement				
Arthritis (n,%)	25, 83%	10, 67%	24, 96%	**0.047**
Mucocutaneous (n,%)	22, 73%	11, 73%	22, 88%	0.369
Lupus Nephritis (n,%)	5, 17%	4, 27%	5, 20%	0.741
Medication				
Hydroxychloroquine (n, %)	25, 83%	14, 93%	24, 96%	0.272
Corticosteroid (n,%)	5, 17%	1, 7%	14, 56%	**0.001**
MMF, MPA, AZA (n,%)	13, 43%	7, 47%	5, 20%	0.124
Fibromyalgia (n,%)	4, 13%	0, 0%	0, 0%	0.059
Admissions in the Past Year (mean ± SD)	1.63 ± 1.52	1.13 ± 1.30	0.52 ± 0.96	**0.009**
Office Visits in the Past Year (mean ± SD)	3.13 ± 2.21	3.20 ± 2.27	4.76 ± 3.35	0.063

610 THE STUDY OF ANTI-MALARIALS IN INCOMPLETE LUPUS ERYTHEMATOSUS (SMILE): AN INTERIM REPORT

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Background Laboratory and clinical features of systemic lupus erythematosus (SLE) may precede the onset of clinically apparent and classifiable disease. Autoantibodies and cytokines have been shown to be present in the blood years before a diagnosis of SLE can be made. Furthermore, nonspecific symptoms such as arthralgias and skin rashes may appear but not be recognized as related to autoimmunity. Patients who have signs, symptoms and laboratory abnormalities associated with SLE but who do not fulfill classification criteria for this condition have been designated as having incomplete lupus erythematosus (ILE). Patients with ILE are at risk for transition to SLE and offer a window into study of therapies that might prevent progressive disease. The SMILE study was designed to investigate whether hydroxychloroquine (HCQ) treatment prevents ILE patients from accumulating additional SLE criteria and developing progressive disease.

Methods SMILE is a multicenter, NIH-funded randomized, placebo-controlled, double blind study of hydroxychloroquine in patients with ILE. Eligible individuals are 15-49 years of age and must have an ANA by IFA of at least 1:80 along with 1 or 2 additional SLICC criteria for SLE. After