

physicians (dermatology or rheumatology). Quota sampling was used to recruit patients from racially and ethnically diverse backgrounds and physicians with varied medical practices. Patient and physician participants provided informed consent. Semi-structured interviews explored patients' experiences with the healthcare system and physicians' challenges when treating patients with lupus.

Results Interviews were conducted with 33 patients and 20 physicians. Age, region, education, employment status, and type/severity of lupus varied among patients, as did physicians' work experience and practice settings (table 1). Patients reported challenges at each step of their journey. Prior to diagnosis, patients entered the healthcare system often lacking awareness of lupus disease and reported feeling initially ignored, dismissed, or misdiagnosed, which delayed treatment and triggered mistrust of the healthcare system. Lack of trust was cited by patients as a reason to discontinue treatment, despite persistent symptoms. Some patients reported perceived challenges with access to branded medications due to insurance coverage or delays in prior authorization and were concerned about losing their job and insurance. Patients communicated that treatment access might be improved by establishing support systems for reliable disease information (advocacy groups, community support), increasing cultural sensitivity in physician practices, and enabling an efficient and transparent treatment initiation process. From the physician perspective, barriers to treatment access included delayed diagnoses, patient concerns over side effects and the need for life-long treatment, communication challenges with patients with limited English proficiency (LEP), and medication costs. Physicians suggested addressing perceived barriers by providing better patient information resources, having a live translator present during visits for patients with LEP, and navigating accessibility to medications through patient assistance programs to ensure access to branded therapies when needed.

Conclusions Improving access to quality care for underrepresented patients is essential to reduce health disparities across racial/ethnic groups and build trust in the healthcare system. Increasing disease awareness among these diverse groups and physicians, establishing patient support networks, and improving patient-physician communication should be critical components of health equity efforts.

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IMPACT STUDY: CAN WE CONDUCT A TRIAL WITH A BIOLOGIC TO PREVENT PREECLAMPSIA IN WOMEN WITH ANTIPHOSPHOLIPID SYNDROME?

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Background Pregnant women with antiphospholipid antibodies and/or lupus have higher rates of adverse pregnancy outcomes (APOs), such as fetal loss and preterm birth due to severe preeclampsia (PE) or placental insufficiency (PI). The presence of lupus anticoagulant (LAC) is the strongest predictor of an APO. At present, there is no effective treatment for women with these high-risk pregnancies, but in an animal model that mimics this human condition we found that TNF- α was a

critical downstream effector of abnormal placental development and fetal damage, and that TNF- α blockade normalized placentation and spiral artery remodeling, and rescued pregnancies. We sought to determine whether TNF- α blockade during pregnancy, added to a regimen of heparin and low dose aspirin, reduces the rate of APOs in women with clinical APS and LAC.

Methods The IMPACT Study (IMProve Pregnancy in APS with Certolizumab Therapy) is an open label single-stage Phase II trial to evaluate the effect of certolizumab, a TNF- α inhibitor that does not cross the placenta and has been shown to be well tolerated in pregnancy, to reduce the risk of adverse outcomes in this population. Patients with APS and LAC are referred to IMPACT by their physicians (often before a planned pregnancy), consented and screened remotely by a study investigator, and medication is sent to the patient. They are treated with certolizumab from gestational week 8 through 28. Investigators contact patients every 2 weeks and receive medical reports and research blood samples monthly. Without the intervention being studied, 44% of these pregnancies were predicted to have serious complications, including severe preterm preeclampsia, growth restricted fetuses, and/or fetal death. Assuming a target 50% reduction in APO rate with the intervention, forty-five evaluable pregnancies are required for 90% power to prove that the intervention reduces the rate of adverse outcomes.

Results Since May 2017, we have enrolled 33 patients from nine states. Characteristics: 61% had previous PE or PI <34 weeks requiring delivery, 70% had previous fetal death >10 weeks, 12% had neonatal death due to complications of prematurity; 42% venous thrombosis, 24% Stroke/TIA, 24% SLE. There have been no study drop-outs.

Conclusion We are successfully using a 'rare disease study' approach to conduct the first trial of a biologic therapy to prevent pregnancy complications women with APS and LAC. For rare conditions such as this, one must target assorted specialists (maternal-fetal medicine, hematology, rheumatology) for recruitment. Identifying patients preconceptionally is ideal, because improving placental vascularization requires enrollment early in pregnancy, and screening evaluations take time. Despite regulatory and logistic complexities and the small number of patients meeting inclusion criteria, their enthusiasm and that of their physicians has allowed us to move forward, albeit slowly.

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PATIENT AND PHYSICIAN PERSPECTIVES OF LUPUS FLARE

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Background Lupus flares can be associated with increased damage, poor outcomes and decreased health-related quality of life. Patients and providers may differ about the nature of a flare, however, complicating communication and

management. Herein, we explored patient and physician descriptions of lupus flares.

Methods We conducted a qualitative descriptive study using in-depth interviews with a purposeful sample of SLE patients (1997 ACR or SLICC criteria) selected for age, race, sex and nephritis; we also interviewed a range of rheumatologists. Interviews were audio-recorded and transcribed. The data were analyzed using applied thematic analysis by a team of qualitative analysts and rheumatologists.

Results We interviewed 42 SLE patients (mean age 45, 93% female, 52% Black, 52% college educated, 15 mean years of disease, 33% historical nephritis). The majority of patients described flare symptoms as joint pain, fatigue, and rashes. Other common symptoms included swelling, myalgias, mood disturbance and flu-like symptoms. Several patients noted brain fog and weakness as flare symptoms. One patient included nephritis and one noted lab abnormalities as signs of flare. According to patients, the majority of flares lasted a matter of days although some quantified flare length as weeks or months. Patients considered stress as the most common trigger.

Thirteen rheumatologists (mean age 54, 53% Female, 61% non-Hispanic White, mean 25 practice years) from 10 academic and 3 community centers were interviewed. All rheumatologists cared for SLE patients; half had a SLE clinical focus and 75% conducted SLE research. The majority of rheumatologists defined flare as an increase in disease activity, with more than half requiring objective findings while a few incorporated a change in therapy. Around half of rheumatologists included fatigue, pain or patient reported symptoms as part of a lupus flare; however, another 2 specifically excluded patient-reported symptoms. A few rheumatologists acknowledged patient and physician discordant views.

Conclusion Together, these data suggest that patients and physicians have different views of flares. Patients view flares as short-lived periods of fatigue, myalgia and arthralgia often prompted by stress. Providers view flares as an objective increase in lupus inflammation requiring immunosuppression. Appreciating this discrepancy is important since patients could misinterpret their rheumatologist's assessment. Moreover, discounting the patient experience could impair the patient-physician relationship with implications for adherence and outcomes. Further study is needed to understand the immunologic basis of patient flares and determine the best approach to incorporate the patient perspective into clinical assessments and management.

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TRAJECTORY OF DAMAGE ACCRUAL IN SYSTEMIC LUPUS ERYTHEMATOSUS BASED ON ETHNICITY, SOCIOECONOMIC FACTORS AND COMORBIDITIES

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Background The Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SLICC/ACR DI) is associated with increased healthcare cost and mortality. We compared the trajectory of total and individual damage items of the SLICC/ACR DI in African-American vs Caucasian ethnicities in a large prospective SLE cohort.

We calculated the attributable risk of comorbidities and socioeconomic factors.

Methods Poisson regression was used to calculate the rate of damage per year for each organ. Cox regression modeling was used to determine the association between time to the individual damage item and ethnicity. Pooled logistic regression models of prospective data were used to calculate the population attributable risk (PAR) for each damage organ.

Results We included 2,436 patients: 43% African-American, 57% Caucasian, and 92% female. There was a linear relationship between time since diagnosis and mean SLICC/ACR DI score, with no plateau. Compared to Caucasians, African-Americans had a faster total, renal, pulmonary, and skin damage accrual rate. Hypertension contributed to 30% of total damage, 70% of renal and 40% of cardiovascular damage. The three socioeconomic measures (education, income, and insurance) accounted for only about 10% of any organ damage and contributed approximately equally to total damage.

Conclusions The linear increase in damage in both ethnicities over time is of particular concern. Ethnicity and hypertension are both important contributors to organ damage in SLE, but socioeconomic factors play a lesser role.

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THE TYPE 1 & 2 SLE MODEL: THE PERSPECTIVE OF PATIENTS AND RHEUMATOLOGISTS

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Background We have proposed a new model that divides SLE manifestations into Type 1 (objective signs of inflammation) and Type 2 (generalized pain and fatigue not clearly due to inflammation). We sought the opinions of patients and rheumatologists to assess the model's face-validity based on their experience living with and/or managing SLE.

Methods Recorded interviews were conducted and analyzed with 42 adults with SLE and 13 rheumatologists. Patients were purposefully recruited to reflect a spectrum of active and inactive Type 1 and 2 SLE. Clinicians were intentionally selected to include leading experts in SLE and community rheumatologists.

Results Most patients approved of the Type 1 & 2 SLE model and several patients said it was 'spot on.' Almost all patients accurately characterized their experience with SLE as having more Type 1, 2, or Mixed symptoms based on their clinical history. One patient with predominantly Type 2 symptoms felt that she had only Type 1 disease as she believed inflammation caused her chronic pain and fatigue. Two patients had difficulty separating Type 1 and 2 symptoms, one having only experienced these together and the other feeling the categorization was 'limiting and binary.' Many patients discussed the connection between their Type 1 & 2 symptoms.

The majority of rheumatologists approved of the model. Many reported using a similar approach and found the addition of specific labels helpful. They felt it could be useful for counseling patients on symptom etiology and the expected impact of medications. Some felt applying the model in patient care could help them determine their therapeutic approach. Several rheumatologists emphasized that Type 2