in the duration of clinic visits during the intervention period (table 2). Among 49 patients who completed surveys, satisfaction with care remained high (table 3).

In interviews, most providers found SLE@Duke helpful to guide conversations and validate patients' feelings. Suggestions to improve SLE@Duke included a shortened PRO measure, more training on scoring PGAs, a referral network for Type 2 SLE symptom management, and more resources for patients and providers about Type 1 & 2 SLE.

Conclusion Through SLE@Duke, our general rheumatologists increased their discussion of Type 2 SLE symptoms without significantly increasing the duration of clinic visits. All patients remained highly satisfied with their care. Future work will take this intervention to other rheumatology clinics to determine its impact on patient outcomes.

Trial Registration NCT05426902

Lay Summary In this pilot study, we assembled tools to discuss the Type 1 & 2 SLE Model, collectively called SLE@Duke. By implementing the Type 1 & 2 SLE Model, our general rheumatologists increased their discussion of Type 2 SLE symptoms without significantly increasing the duration of clinic visits. All patients remained highly satisfied with their care.

Abstract 615 Table 1 Provider acceptability, appropriateness, and feasibility of the intervention.

	Pre-Intervention (n=12)	Post-Intervention (n=12)	
Acceptability	Mean (SD)	Mean (SD)	p-value
The intervention meets my approval.	4.1 (0.5)	4.0 (0.6)	0.7
The intervention is appealing to me.	4.0 (0.6)	4.0 (0.6)	1.0
I like the intervention.	4.1 (0.7)	3.9 (0.7)	0.5
I welcome the intervention.	4.2 (0.7)	4.0 (0.7)	0.6
Appropriateness			
The intervention seems fitting.	4.2 (0.6)	4.1 (0.7)	0.7
The intervention seems suitable.	4.2 (0.6)	4.1 (0.7)	0.7
The intervention seems applicable.	4.2 (0.6)	4.2 (0.6)	1.0
The intervention seems like a good match.	4.2 (0.6)	4.2 (0.6)	1.0
Feasibility			
The intervention seems implementable.	4.0 (0.6)	4.3 (0.6)	0.3
The intervention seems possible.	4.0 (0.6)	4.3 (0.5)	0.3
The intervention seems doable.	4.1 (0.5)	4.3 (0.5)	0.4
The intervention seems easy to use.	3.6 (0.9)	4.0 (0.9)	0.3

**1 = completely disagree, 2 = disagree, 3 = neither agree/disagree, 4 = agree, 5 = completely agree*

Abstract 615 Table 2 Change in outcomes in the electronic medical record.

	Pre-Intervention (n=36)	Intervention (n=31)	p-value
Duration of visit, minutes (median, IQR)	64.5 (57.5-86.5)	69.5 (47-85)	0.9
Type 1 & 2 PGAs in note	0 (0%)	27 (87%)	<0.0001
Type 2 SLE symptoms discussed	16 (44%)	23 (74%)	0.02
Type 2 SLE treatments discussed	5 (14%)	8 (26%)	0.4

Abstract 615 Table 3 Change in patient satisfaction before and during the intervention.

	Pre-Intervention (n=19)	Intervention (n=30)
	n (%)*	n (%)*
I feel good about my medical visit.	16 (84%)	23 (79%)
My rheumatologist and I agreed on how active my lupus was today.	16 (84%)	24 (80%)
My rheumatologist gave me his/her full attention.	17 (89%)	26 (87%)
I was able to say everything I wanted to say to my rheumatologist.	18 (95%)	26 (87%)
I understand the care recommendations that my doctor or provider gave me today.	17 (89%)	26 (87%)

*number and percent of patients responding they "strongly agree."

Clinical Research in SLE

616 LOWER HYDROXYCHLOROQUINE BLOOD LEVELS ARE ASSOCIATED WITH HIGHER TYPE 1 AND 2 LUPUS ACTIVITIES

[1]Kai Sun, [1]Jennifer Rogers, [1]Amanda Eudy, [1]Lisa Criscione Schreiber, [1]Rebecca Sadun, [1]Jayanth Doss, [2]Kelley Brady, [2]Roberta Vezza Alexander, [2]John Conklin, [1]Megan Clowse. *[1]Duke University Medical Center, USA; [2]Exagen Inc., USA*

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Background Hydroxychloroquine (HCQ) is a mainstay of the initial and long-term treatment of systemic lupus erythematosus (SLE). HCQ blood levels can reflect adherence to the medication and have been correlated with SLE outcomes. However, little is known about the relationship between HCQ levels and SLE disease activity according to the Type 1 & 2 SLE Model, in which Type 1 activity is thought to be mediated by inflammation, e.g., arthritis, rash, nephritis, and Type 2 manifestations have uncertain relationship to inflammation, e.g., fatigue, myalgias, mood disturbance, and cognitive dysfunction.

Method Patients meeting the 1997 American College of Rheumatology or 2012 Systemic Lupus International Collaborating Clinics classification criteria for SLE were recruited from an academic lupus clinic. Whole blood HCQ levels were measured in Exagen's clinical laboratory using liquid chromatography coupled to mass spectrometry and were categorized as under-exposure (HCQ <200 ng/ml), subtherapeutic (HCQ between 200-1000 ng/ml), or therapeutic HCQ Levels (HCQ >1000 ng/ml). Type 1 SLE activity was measured by Type 1 Physician Global Assessment (PGA) and Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). Type 2 SLE activity measures included Type 2 PGA and patient-reported Polysymptomatic Distress (PSD) score (sum of widespread pain index and symptom severity score). Type 1 and 2 SLE Model classifications are defined in table 1. Self-reported adherence to HCQ was measured using the visual analog scale of the Medication Adherence Self-Report Inventory.

We examined demographic and clinical differences among patients with different HCQ blood levels using the Chi-squared and Kruskal-Wallis tests. We also examined the distribution of HCQ levels across different types of lupus activities.

Results This cross-sectional analysis included 156 patients (median age 42, 91% female, 61% black, 43% married or cohabiting, 60% with annual household income ≤$50,000, and 47% with Medicaid/Medicare insurance). In this cohort, 32% were classified to have Minimal SLE (low Type 1 & 2 activity), 12% had active Type 1 with low Type 2 SLE activity, 24% had active Type 2 with low Type 1 SLE activity, and 32% had Mixed SLE (high Type 1 & 2 activity).

Of the 127 patients who provided adherence data, 70% reported ≥90% adherence to the prescribed dose. HCQ whole blood levels were in the under-exposure range in 19%, subtherapeutic in 35%, and therapeutic in 46% of patients (table 2).

No significant differences in sociodemographics, dosing parameters, HCQ dose, and self-reported adherence were found among patients with under-exposed, subtherapeutic, and therapeutic HCQ levels.

Abstract 616 Table 1 Classifications of the Type 1 and 2 SLE model.

	Low Type 2 SLE Activity (FSS ≥8 or PGA ≥1.0)	High Type 2 SLE Activity (FSS <8 and PGA <1.0)
Low Type 1 SLE Activity (SLEDAI <6, clinical SLEDAI <4, no active nephritis, and PGA <1.0)	Minimal SLE	Type 2 SLE
High Type 1 SLE Activity (SLEDAI ≥6, clinical SLEDAI ≥4, active lupus nephritis, or PGA ≥1.0)	Type 1 SLE	Mixed SLE

Lower HCQ levels were significantly associated with both higher Type 1 and Type 2 SLE activities. Patients with lower HCQ levels self-reported more polysymptomatic distress, widespread pain, and symptoms severity, as well as a trend for more cognitive dysfunction and depression (table 3). There is a trend that patients with Mixed SLE activity were more likely to have under-exposed HCQ levels (table 4).

Conclusion More than half of the patients had lower than therapeutic HCQ blood levels, but self- reported adherence was similarly high across the groups, highlighting the importance of using objective adherence assessments. Surprisingly, lower HCQ levels were associated with both higher Type 1 and Type 2 SLE activity. Although Type 2 SLE manifestations have unclear relationship to inflammation, their inverse association with HCQ blood levels, particularly among patients with concurrent Type 1 SLE activity, suggest that in some SLE patients, immunologic activity may play a role in these chronic debilitating symptoms. Our data also suggests that perhaps low HCQ blood levels allow inflammatory Type 2 SLE symptoms to be active. Future study should explore the longitudinal relationship between HCQ levels and Type 1 and 2 SLE activities.

Lay summary A novel model classifies different lupus symptoms into Type 1 & 2 lupus activity. In this model, symptoms that are known to be mediated by inflammation, such as arthritis, rash, and kidney involvement by lupus are classified as Type 1 lupus activity; symptoms that have unclear relationship to inflammation, such as fatigue, brain fog, and widespread pain are classified as Type 2 lupus activity.

Hydroxychloroquine (HCQ) is one of the most important lupus medications, and we know that taking HCQ consistently is important to control inflammation (Type 1 lupus activity),

Abstract 616 Table 2 Comparing socio-demographics, self-reported adherence, and HCQ dosing information among patients with different HCQ levels.

	Total cohort (n=156)	Under-exposed HCQ (n=30)	Subtherapeutic HCQ (n=55)	Therapeutic HCQ (n=71)	p- value
Socio-demographics					
Age in years	42.3 (13.7)	40.0 (14.4)	41.8 (13.1)	44.8 (13.7)	0.2
Female gender	142 (91%)	26 (87%)	50 (91%)	66 (93%)	0.6
Black (n=150)	92 (61%)	5 (56%)	36 (68%)	41 (59%)	0.4
Less than a College Education (n=138)	55 (40%)	16 (57%)	17 (35%)	22 (36%)	0.1
Married/cohabitating (n=142)	61 (43%)	11 (39%)	24 (48%)	26 (41%)	0.7
Income < $50,000 (n=135)	81 (60%)	20 (71%)	29 (64%)	32 (52%)	0.2
Medicare, Medicaid or Uninsured (n=136)	64 (47%)	16 (59%)	21 (44%)	27 (44%)	0.4
Self-reported adherence ≥90% (n=127)	89 (70%)	13 (57%)	31 (66%)	45 (79%)	0.1
Creatinine (n=152)					0.2
<1.4	137 (90%)	25 (89%)	49 (92%)	63 (89%)	
1.4-4.9	13 (9%)	3 (9%)	2 (4%)	8 (11%)	
≥5	2 (1%)	0 (0%)	2 (4%)	0 (0%)	
HCQ dose (n=152)					0.7
>5mg/kg	39 (26%)	8 (27%)	14 (26%)	17 (25%)	
4-5mg/kg	53 (35%)	12 (40%)	15 (28%)	26 (38%)	
<4mg/kg	60 (39%)	10 (33%)	25 (46%)	25 (37%)	
Weight in kg (n=157)	85.6 (27.7)	79.9 (19.5)	88.2 (32.1)	86.0 (26.9)	0.4
Median (IQR)	83 (64-101.3)	79.8 (64-90.7)	77.4 (62-113)	84.8 (65.1-99.4)	0.7

Footnotes: continuous variables are summarized by mean (standard deviation)

Abstract 616 Table 3 Comparing measures of Type 1 and Type 2 SLE activity among patients with different HCQ levels.

	Under-exposed HCQ (n=30)	Subtherapeutic HCQ (n=55)	Therapeutic HCQ (n=71)	p-value
Type 1 SLE Activity:				
Type 1 PGA	0.8 (0.6)	0.6 (0.6)	0.6 (0.6)	0.08
Type 1 PGA ≥1	**18 (60%)**	**15 (27%)**	**19 (27%)**	**0.004**
Active LN	5 (18%)	4 (7%)	9 (13%)	0.3
SLEDAI	**4.4 (4.3)**	**2.7 (3.6)**	**2.7 (2.8)**	**0.05**
Clinical SLEDAI	**2.5 (2.8)**	**0.9 (1.9)**	**1.2 (2.2)**	**0.006**
Type 2 SLE Activity:				
Type 2 PGA	**1.0 (0.7)**	**0.6 (0.6)**	**0.7 (0.6)**	**0.03**
Type 2 PGA ≥1	**18 (60%)**	**17 (31%)**	**28 (39%)**	**0.03**
Polysymptomatic Distress Score[1]	**13.0 (8.0)**	**8.2 (6.7)**	**7.8 (6.1)**	**0.003**
Widespread Pain Index	**5.6 (5.2)**	**3.7 (4.2)**	**3.1 (3.5)**	**0.03**
Symptom Severity Score	**6.6 (4.2)**	**4.5 (3.2)**	**4.6 (3.2)**	**0.02**
Fatigue[2]	14 (58%)	26 (54%)	24 (44%)	0.5
Cognitive dysfunction[2]	9 (41%)	11 (24%)	9 (17%)	0.08
Unrefreshed sleep[2]	13 (54%)	19 (40%)	18 (33%)	0.2
Depression[2]	15 (65%)	22 (46%)	19 (37%)	0.09

Footnotes: continuous variables are summarized by mean (standard deviation); [1]Polysymptomatic distress score is the sum of widespread pain index and symptom severity score; [2]Fatigue, cognitive dysfunction, unrefreshing sleep, and depression are components of the symptom severity score; the percentage of patients reporting moderate-severe levels of these symptoms.

Abstract 616 Table 4 Comparing HCQ levels across SLE groups.

	Minimal (n=51)	Mixed (n=50)	Type 1 (n=18)	Type 2 (n=37)	p-value
HCQ level, ng/ml, median (IQR)	922 (486-1247)	664 (60-1322)	1080 (660-1160)	1033 (429-1416)	0.2
Under-exposed HCQ (n=39)	5 (10%)	17 (34%)	2 (11%)	6 (16%)	0.06
Subtherapeutic HCQ (n=55)	23 (45%)	15 (30%)	5 (28%)	12 (32%)	
Therapeutic HCQ (n=71)	23 (45%)	18 (36%)	11 (61%)	19 (51%)	

Footnotes: continuous variables are summarized by median (interquartile range); Minimal = low type 1 & 2 SLE activity; mixed = high type 1 & 2 SLE activity; type 1=high type 1 but low type 2 SLE activity; Type 2 = high type 2 but low type 1 SLE activity.

but we have limited information on how HCQ may help with type 2 lupus activity.

In this study, we tested HCQ blood levels in patients with lupus taking this medication and found that levels were low in more than half of the patients, suggesting that these patients were not taking the medication consistently. Patients with low HCQ levels had higher Type 1 and Type 2 lupus activities compared to patients with higher HCQ levels. Our findings suggest that in some patients, Type 2 lupus activity is related to inflammation, and having low HCQ levels is allowing the inflammatory Type 2 lupus symptoms to be active.

617 EVALUATION OF SLE OUTCOME MEASURES IN TELEMEDICINE: INTERIM ANALYSIS RESULTS

[1]Anca D Askanase*, [2]Cynthia Aranow, [3]Mimi Kim, [4]Diane Kamen, [5]Cristina Arriens, [1]Wei Tang, [1]Leila Khalili, [1]Julia Barasch, [6]Maria Dall'Era, [2]Meggan Mackay. *[1]Division of Rheumatology, Columbia University Irving Medical Center, New York, NY, USA; [2]Center for Autoimmunity, Musculoskeletal and Hematologic Diseases, Feinstein Institute for Medical Research, New York, NY, USA; [3]Department of Biostatistics, Albert Einstein College of Medicine, Bronx, NY, USA; [4]Division of Rheumatology and Immunology, Department of Medicine, Medical University of South Carolina, Charleston, SC, USA; [5]Department of Arthritis and Clinical Immunology, Rheumatology, Oklahoma Medical Research Foundation, Oklahoma City, OK, USA; [6]Division of Rheumatology and Russell/Engleman Rheumatology Research Center, University of California San Francisco, San Francisco, CA, USA*

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Background Telemedicine (TM) became central to rheumatology care during the COVID-19 pandemic. Accumulating evidence suggests high acceptance, satisfaction, and feasibility of TM. There is a paucity of data on the use of TM in systemic lupus erythematosus (SLE). Due to the complexity of SLE outcome measures, clinicians and clinical trialists have raised concerns about the accuracy of TM-derived disease activity measures. This study aims to evaluate the level of agreement between physician-assessed virtual and face-to-face SLE outcome measures. Here we describe the study design and data on the first 50 participants evaluated.

Purpose To investigate whether physician assessments of SLE disease activity obtained during TM visits are comparable with those obtained during face-to-face (F2F) visits.

Methods This is an observational, longitudinal study of 200 SLE participants with varying levels of disease activity from 4 academic lupus centers serving diverse populations. The study is supported by the US Department of Defense. Each study participant is evaluated at 2 visits (baseline and a follow-up visit) as dictated by usual care. Virtual physical exam guidelines were established, and rely on physician-directed patient self-examination of major organ systems. At each visit, participants are evaluated by the same physician first via videoconference-based TM immediately followed by a F2F encounter. SLE disease activity measures (BILAG, hybrid SLEDAI, PGA, LFA-REAL™, CLASI, Swollen and Tender Joint Count [TSJC] and CGIC) are completed after the TM encounter and repeated after the F2F encounter. Tandem physician and participant feedback tools for TM and F2F encounters assess satisfaction, comfort, and which portion of the physical exam was difficult to evaluate virtually. In a pre-planned interim analysis of data from the first 50 participants, the degree of agreement between TM and F2F disease activity measures was analyzed using the paired-T-test and intra-class correlations (ICC). Bland-Altman plots of the differences between TM and F2F and scatter plots were also generated.

Results 50 participants were enrolled, 25 completed the follow-up visit. The baseline characteristics are summarized in table 1, 82% women, mean age 38.9 ± 13. The current enrollment spans a wide range of physician determined categories of disease activity (25% inactive, 56% mild/moderate, 18% severe). The study population is racially and ethnically diverse. The mean differences between TM and F2F in various disease activity measures showed that TM tended to slightly underestimate disease activity, but the differences were not statistically significant (table 2).