

**Abstract 619 Table 1** Antibody titers by race/ethnicity and maternal diagnosis.

	Number of Patients N = 238*	Anti-Ro52 Titer Median [IQR]	p-value	Anti-Ro60 Titer Median [IQR]	p-value
Race/Ethnicity			0.500		0.704
Non-Hispanic White	118 (49.6%)	3064 [400, 12488]		4613 [417, 14322]	
Non-Hispanic Asian	29 (12.2%)	1021 [348, 9447]		3367 [349, 21597]	
Black	28 (11.7%)	912 [385, 3172]		876 [178, 9939]	
Hispanic	53 (22.3%)	990 [404, 7073]		3259 [227, 11791]	
Other	10 (4.2%)	680 [374, 3754]		1807 [612, 15571]	
Maternal diagnosis	N=161		0.195		0.176
Asym/UAS	63 (39.1%)	2239 [418, 12203]		5190 [463, 17836]	
RA	17 (10.6%)	3556 [250, 10199]		580 [185, 9380]	
SS	50 (31.1%)	3827 [770, 14803]		6703 [583, 28353]	
SLE	31 (19.3%)	1042 [401, 5674]		3364 [314, 12054]	

\*Two referred previous AVB patients had unexpectedly low titer but were provided with Dopplers.

**Abstract 619 Table 2** Adverse pregnancy outcomes by maternal diagnosis.

Maternal Diagnosis	Total Number Delivered N=95	Delivered APO N=20	p-value
			<0.006
Asym/UAS	30	6 (20%)	
RA	11	2 (18%)	
SS	34	3 (9%)	
SLE	15	9 (60%)	

either reassured if FHRM was normal or referred for emergency fetal echo in < 6 hours if abnormal.

**Results** 250 anti-Ro pregnant women (22% Hispanic, 50% white, 12% Black, 12% Asian, 4% other) have been consented, including 28 whose previous child had AVB. Of mothers tested to date, 153 were provided home monitors given high titer anti-Ro60 and/or 52 antibodies (26 high titer anti-Ro60 alone, 21 high titer anti-Ro52 alone, 105 high titer antibodies to both antigens).

The 83 patients with low titers were surveilled with echos per local standard of care. Regarding maternal diagnosis, of 161 assessed to date, 39% were asym/UAS, 11% RA, 31% SS, 19% SLE. Antibody titers did not significantly differ by ethnicity, race or diagnosis (table 1). Non-AVB APOs occurred in 18% and were not predicted by Ro60 or 52 titers but rather SLE diagnosis (table 2). In total, 24,759 FHRM audio-texts were received from 131 patients (90 of whom have delivered) during the monitoring period. Of these, 22 were evaluated by the on-call pediatric cardiologist, who prompted an emergency echo (all completed in < 6 hrs). In 11 cases, the emergency echo was normal. In 9, there were premature atrial contractions, confirming the mother's perception. In 2 with 2° block on urgent echo (both treated per protocol with IVIG and dexamethasone), 1 reverted to normal sinus rhythm and the other progressed to 3° block. In 2 others, the mother did not perceive abnormal FHRM for > 24 hrs, echo identified 3° block, and retrospective cardiology review of FHRM audio captures identified an abnormality prior to obtaining the echo. All 4 AVB developed in fetuses of mothers with high titer antibodies to both Ro60 and 52 (mean 32,451 and 34,991 respectively). Of the 18 mothers with a previous AVB

child who followed the 400mg hydroxychloroquine PATCH protocol, 1 developed AVB in accord with the results of Step 1 in that study.

**Conclusion** These data support that APOs in this clinically diverse group of mothers are not influenced by anti-Ro titer or specificity, but rather SLE diagnosis. All conduction defects were initially identified by FHRM and in mothers with high titer anti-Ro60 and 52. Hydroxychloroquine continues to show efficacy in reducing the AVB recurrence rate with rapid intervention of emergent block being promising.

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### CREATING A CULTURE OF CLINICAL RESEARCH IN THE CLINIC: INTEGRATING CLINICAL TRIALS INTO THE CARE OF PATIENTS WITH LUPUS

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10.1136/lupus-2022-lupus21century.41

**Background** The prevalence of systemic lupus erythematosus (SLE) is substantially greater among racial and ethnic minorities. However, marked gaps exist between populations affected by SLE and those enrolled in clinical trials, even large-scale multicenter and multinational trials.<sup>1, 2</sup> A lack of diverse populations in lupus clinical trials results in an evidence base that is less generalizable to underrepresented patients who may be more severely impacted by this disease, further exacerbating existing health disparities.<sup>2, 3</sup> In order to cultivate a culture to integrate clinical trials in clinical care settings, we must strive to equip clinicians with the motivation, skills, and proficiency to inform and encourage effective conversations with diverse patients about lupus clinical trial participation. We aimed to explore available evidence on the importance of and approaches for patient-clinician communication around clinical trials and outline opportunities for future research to advance clinician communication around lupus clinical trials.

**Methods** Based on a review of the available evidence, we provide an overview of: 1) the state of diversity and representation in lupus clinical trials; 2) the critical role, responsibility, and potential clinicians have in integrating lupus clinical trials into lupus clinical care; and 3) expert-informed guidance and opportunities for future research to improve diversity and representation in lupus clinical trials.

**Results** There has been limited attention given specifically to clinical trials discussions in communication programs developed for providers,<sup>4,7</sup> and to our knowledge, **none specifically tailored to improving clinicians' communication skills to improve conversations with racially and ethnically diverse patients with lupus about participation in clinical trials.** In order to cultivate a culture of research in clinical practice, early exposure and training for clinicians is critical to impart understanding and a sense of importance of the potential opportunities for patients to benefit from clinical research.<sup>8</sup> Clinician communication with patients has been identified as one of the most effective approaches to increase enrollment in clinical trials and healthcare research,<sup>9</sup> and many patients expect and prefer their treating physicians to inform them about clinical trial opportunities.<sup>10, 11</sup> As there is no formal training pathway for trainees or clinicians who want to become more involved in clinical trials, or wish to pursue a career as a clinical trialist, there is a clear need to provide such opportunities. Academic medical settings present multiple advantages to care and research (e.g., subspecialty expertise and training, clinical trial infrastructure).<sup>12</sup> Thus it is critical that trainees and clinicians are provided with education, training, and practical experiences such as apprenticeships with experienced investigators to learn about clinical investigation. Clinicians can adopt a 'universal precautions' approach to

lupus clinical trial discussions in the context of clinical care.<sup>13</sup> Such an approach can address clinician implicit biases and ensure that all potentially eligible patients are provided the opportunity to make informed decisions about participation in a lupus clinical trial. Additional education, training, and support are needed to equip clinicians with the skills to carry out effective clinical-trial discussions with patients, such as verbal and nonverbal skills training, cultural competence, and implicit bias training (table 1).<sup>4, 14-18</sup> Improved patient-clinician communication can in turn increase trust in the clinician, build rapport, and improve patients' consideration of participation in lupus clinical trials.<sup>5, 19, 20</sup>

**Conclusions** Improving equity in patients' opportunities to participate in lupus clinical trials is essential to address disparities in clinical trial participation, and ultimately improve health outcomes. In order to cultivate a culture of research in clinical practice and improve diversity and representation in lupus clinical trials, it is critical that we integrate formal training and learning opportunities for trainees and clinicians who will care for patients with lupus. Research is needed to understand and identify best practices to support effective patient-clinician communication to facilitate patient engagement and participation in lupus clinical trials.

**Acknowledgments** Abstract presented on behalf of the Chapel Hill Alliance Promoting Excellence in Lupus (CHAPEL) group of investigators. We would like to acknowledge individuals living with lupus for their courage and determination, and clinical trial participants for their contributions to science and efforts in advancing health and healing for all.

**Lay Summary** There is an urgent need to improve the participation of racially and ethnically diverse participants in lupus clinical trials to ensure that the products from clinical trials

**Abstract 620 Table 1** Clinician-focused opportunities and approaches to cultivate a culture of clinical research in lupus clinical care

Strategy	Strategies to cultivate a culture of clinical research in clinical care	Future directions and opportunities
<b>Provide training opportunities for trainees and clinicians</b>	<ul style="list-style-type: none"> <li>• Provide subspecialty fellows/trainees with formal training, practical experience/ apprenticeship, and mentorship opportunities to gain experience in clinical trials investigation</li> <li>• Develop and integrate formal training programs throughout medical training and continuing education to develop and strengthen skills and expertise in having effective clinical trial conversations (e.g., verbal and nonverbal skills training, cultural competence and implicit bias training)</li> <li>• Adopt/integrate existing programs such as Materials to Increase Minority Involvement in Clinical Trials (MIMICT), an online accredited CME program through the ACR that focuses on improving clinician knowledge about referring diverse patients to lupus clinical trials<sup>21</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Engage diverse stakeholders, including patients, throughout all phases of the development, evaluation, and dissemination of training products</li> </ul>
<b>Adopt a 'Universal Precautions' Approach to Educate All Patients About Clinical Trials</b>	<ul style="list-style-type: none"> <li>• Present clinical trial opportunities to all potentially eligible patients (e.g., regardless of beliefs or implicit biases around a patient's willingness to participate or 'fit' for a trial)</li> <li>• Advocate for consideration of participation, rather than participation<sup>11</sup></li> <li>• Offer additional resources for patients to support informed decisions about clinical trial participation</li> <li>• Incorporate teach-back methods to train research personnel as well as to reinforce patient education and understanding</li> <li>• Develop clinical trials materials (including consent forms) in languages other than English</li> </ul>	<ul style="list-style-type: none"> <li>• Explore patient preferences for conversations with clinicians about lupus clinical trials</li> <li>• Develop culturally competent, health literate lupus clinical trial-specific information and research materials to support patients in making informed decisions</li> <li>• Diversify clinical research personnel (e.g., bilingual research staff, etc.)</li> </ul>
<b>Provider Outreach</b>	<ul style="list-style-type: none"> <li>• Engage, exchange information, and build partnerships with rheumatologists, as well as primary care physicians and subspecialists who are closely involved in the care of patients with lupus, as well as health care and research teams</li> </ul>	<ul style="list-style-type: none"> <li>• Conduct outreach to create communication and partnerships between academic and private- practice settings</li> <li>• Encourage outreach to and partnerships with community organizations and stakeholders</li> </ul>

are safe and effective for all patients. Clinician communication with patients has been identified as one of the most effective approaches to increase enrollment in clinical trials and health-care research.

However, there is no formal training for trainees or clinicians who want to become trial investigators or more involved in clinical trials. There is a clear need to provide such opportunities for both practicing clinicians and trainees to build knowledge and skills around having effective conversations with patients about lupus clinical trials and provide all eligible patients with the opportunity to make decisions about participation in a clinical trial.

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## Clinical Research in SLE

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### THE ASSOCIATION OF INTERFERON WITH KYNURENINE/TRYPHTOPHAN PATHWAY ACTIVATION IN SYSTEMIC LUPUS ERYTHEMATOSUS

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10.1136/lupus-2022-lupus21century.42

**Background** Cognitive dysfunction (CD) is highly prevalent in systemic lupus erythematosus (SLE) with significant impact on quality of life, yet SLE-mediated mechanisms for CD remain poorly understood. Quinolinic acid (QA), a metabolite of the kynurenine (KYN)/tryptophan (TRP) pathway, is a N-methyl-

**Abstract 621 Table 1 SLE and healthy control (HC) subject characteristics and KYN/TRP pathway metabolite ratios.** All data is reported either as a mean (or median where indicated) ± standard deviation (or interquartile range), or as a frequency (%). All data refers to that which was collected at the time of evaluation

Subject characteristics	SLE (N = 72)	HC (N = 73)	p
<b>Age</b> (mean # years ± SD, range)	37.9 ± 9.6 (22 – 57)	36.2 ± 9.5 (18 – 55)	0.28
<b>Ethnicity</b> (Hispanic/Latino)	13 (18.1%)	13 (17.8%)	0.97
<b>Race</b> Black	43 (59.7%)	41 (56.2%)	0.91
White	16 (22.2%)	18 (24.7%)	
Other	13 (18.1%)	14 (19.2%)	
<b>KYN/TRP ratio</b>	<b>0.04 ± 0.03</b>	<b>0.03 ± 0.01</b>	<b>&lt;0.01</b>
Median ± IQR (range)	<b>(0.01 - 0.23)</b>	<b>(0.01 - 0.13)</b>	
<b>QA/KA ratio</b>	<b>18.4 ± 14.7</b>	<b>8.9 ± 5.8</b>	<b>&lt;0.01</b>
Median ± IQR (range)	<b>(4.0 - 121.2)</b>	<b>(2.9 - 45.9)</b>	
<b>Disease duration</b>	12.3 ± 8.5	n/a	n/a
Mean ± SD (range)	(1 – 38)		
<b>SELENA SLEDAI score</b>	5.4 ± 5.1	n/a	n/a
Mean ± SD (range)	(0 – 29)		
<b>Prednisone dose</b>	2.5 ± 10.0	n/a	n/a
(mg/day; median ± IQR, range)	(0 – 75)		
<b>Current hydroxychloroquine use</b>	54 (75.0%)	n/a	n/a
<b>Current immunosuppressant use</b>	34 (47.2%)	n/a	n/a
<b>Anti-dsDNA positive (&gt; 29 IU/ml)</b>	50 (69.4%)	n/a	n/a
<b>C3 low (&lt; 81 mg/dL)</b>	28 (38.9%)	n/a	n/a
<b>C4 low (&lt; 13 mg/dL)</b>	24 (33.3%)	n/a	n/a