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Alignment of contraception use with the ACR reproductive health guidelines in women with systemic lupus erythematosus within the RISE registry

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ABSTRACT

Objectives Contraception is crucial for safely timing pregnancies in patients with SLE. This study investigated predictors of contraception documentation in patients with SLE, and the alignment of contraception practices with the 2020 American College of Rheumatology (ACR) guidelines, within the Rheumatology Informatics System for Effectiveness (RISE) registry.

Materials and methods Female patients (aged 18–44 years) with SLE were identified via International Classification of Diseases (ICD)-9/ICD-10 coding within the RISE registry, which includes data from rheumatology clinics across the USA. Eligible patients were required to have ≥1 clinical visit in 2019 (prepandemic) or between 1 April 2020 and 30 March 2021 (mid-pandemic). Adjusted multilevel logistic modelling assessed patient, provider and practice characteristics for associations with contraception documentation. Contraception patterns were identified and compared with the 2020 ACR guidelines.

Results Contraception documentation rates were similar in the prepandemic and mid-pandemic groups (8.1% and 8.5%, respectively). Higher documentation rates were found in women who were younger, White, and had more visits, as well as those seen within a health system, by a female provider, and within specific regions and electronic health record (EHR) systems. Prescription of a teratogenic medication did not influence contraception documentation or type. Oestrogen-containing contraceptives were prescribed less often to women at high risk for thrombosis (26.2% with thrombotic risk vs 60.6% without, p<0.0001) and history of lupus nephritis (LN) (53.8% with history of LN vs 63.2% without, p=0.024).

Conclusions Practices participating in the RISE registry do not currently record contraception in the large majority of women with SLE, although increased documentation in some EHRs suggests that system changes may improve rates of documentation. Women at higher risk for thrombosis were less likely to receive oestrogen, suggesting that warnings against oestrogen use has impacted contraception prescription, although the limited documentation and limited contraception among women taking teratogenic medications suggest a high unmet need.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The American College of Rheumatology's reproductive health guidelines recommend contraception for women with SLE to avoid pregnancy when it is not desired or there is a high risk for complications due to active lupus and use of teratogenic medications.

WHAT THIS STUDY ADDS

⇒ Within the Rheumatology Informatics System for Effectiveness registry, documentation of contraception in discrete fields is low, although the frequency of documentation is higher among white women and within some electronic medical records.

⇒ Prescription of a teratogen did not influence the frequency of contraception documentation.

⇒ The use of oestrogen-containing contraceptives is lower among women with a history of lupus nephritis and at increased risk for thrombosis, which is aligned with the guidelines' recommendations.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ If contraception documentation is to become an effective quality measure for women with SLE, practices will need to identify a location within the EHR to systematically document its use.

INTRODUCTION

SLE is an autoimmune disease among women of reproductive age that is associated with a high risk of pregnancy complications. Suitable contraception is therefore a critical aspect of healthcare, allowing patients with SLE to avoid pregnancy during periods of active disease and to plan pregnancies to coincide with periods of disease quiescence.[1 2]

Expanding effective contraception use in patients with SLE is a key strategy for preventing pregnancy complications including maternal mortality, preterm birth and fetal abnormalities due to teratogenic exposure.[1–5] Current patterns of contraception use among patients with SLE, however, is unclear as these data are not systematically

documented in many rheumatology practices. Indeed, our previous study of the RISE registry electronic health record (EHR)-based analyses has shown that in 2018 just 7.9% of patients with SLE had contraception documentation of any kind, with a woman's race and age associated with the likelihood of documentation.[6] Observational studies focusing on patients with contraception documentation have demonstrated low contraceptive rates among those with SLE, particularly for intrauterine devices (IUDs) and hormonal-based contraceptives.[7–9] Additionally, studies have suggested that inadequate proportions of patients with SLE receive contraception consultations or counselling, potentially causing insufficient patient understanding of contraceptive choices.[9–11]

Optimal contraception may differ among patients with SLE due to variations in patient clinical background and prescribed SLE therapeutics. In 2020, the American College of Rheumatology (ACR) released reproductive health guidelines for patients with rheumatic diseases, including medically appropriate contraception recommendations for patients with SLE.[12] These guidelines addressed variations in patient characteristics and provided tailored contraceptive suggestions according to thrombotic risk, SLE activity and use of SLE-related immunosuppressive therapies (figure 1). Key recommendations included encouraging the use of long-acting reversible contraception (LARC) such as IUDs in patients with a high thrombotic risk or highly active SLE, as well as avoiding oestrogen-containing contraceptives.

Alignment of contraceptive practices with the ACR guidelines, however, is currently unclear and in-depth analyses are required to uncover real-world patterns of contraceptive use. The Rheumatology Informatics System for Effectiveness (RISE) registry is a national EHR-enabled registry, sponsored by the ACR, which collects observational data from participating rheumatology practices during routine clinical care across the USA.[13] This study aimed to assess data extracted from the RISE registry to identify predictors of contraception documentation among patients with SLE and to determine the degree

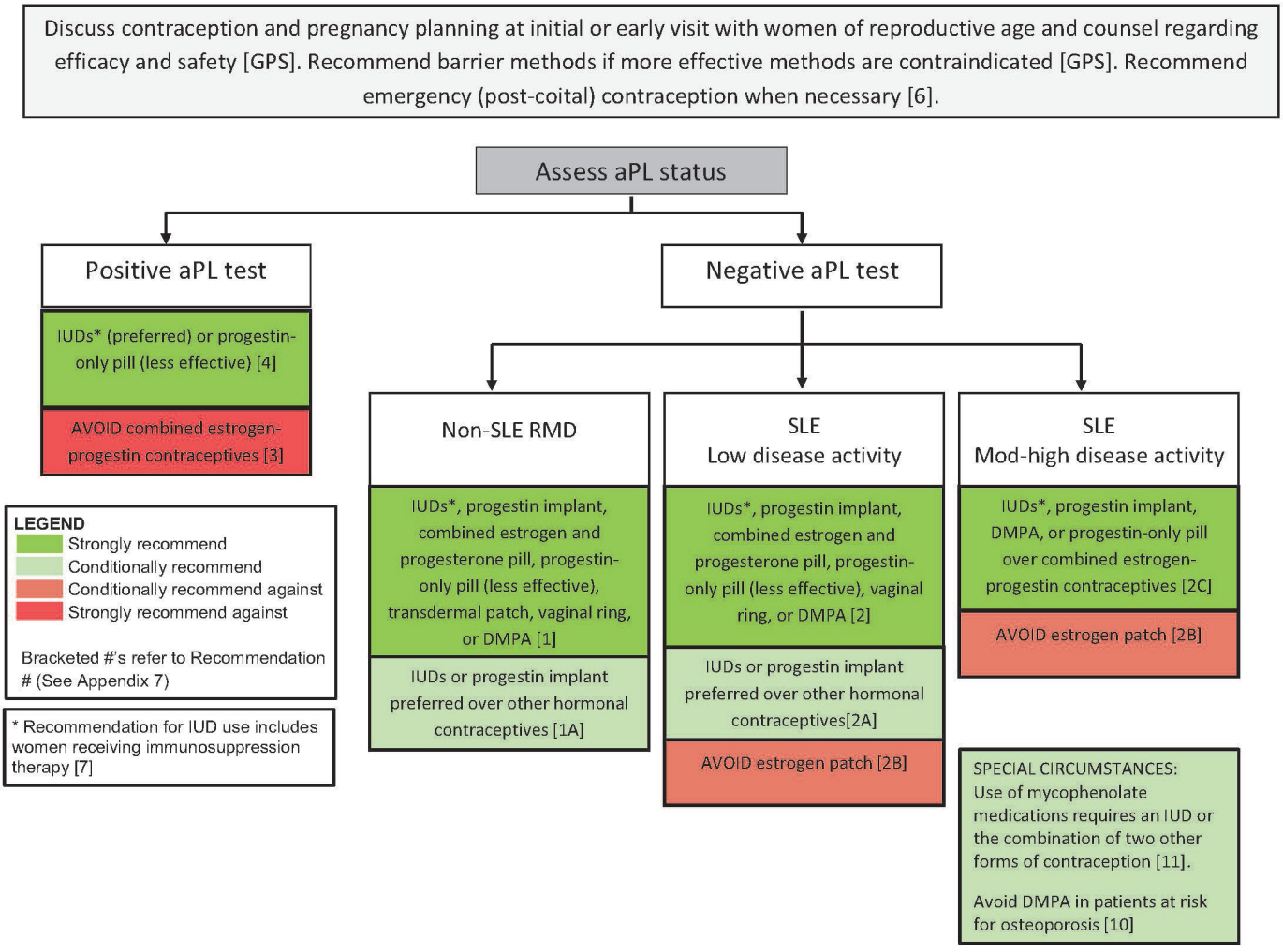

Figure 1 Decision tree of contraception recommendations from the ACR[12] reproductive health guidelines: Recommendations and good practice statements (GPS) for use of contraception in women with rheumatic and musculoskeletal disease (RMD). aPL, antiphospholipid antibody (persistent moderate [Mod]–to-high–titer anticardiolipin or anti–β2-glycoprotein I antibody or persistent positive lupus anticoagulant); IUDs, intrauterine devices (copper or progestin). ACR, American College of Rheumatology; DMPA, depo medroxyprogesterone acetate.

to which current contraception practices are aligned with the ACR 2020 guidelines. Because two events occurred in early 2020 that could impact clinical care and contraception prescription—the global COVID-19 pandemic and the publication of the ACR's reproductive health guidelines—we divided the study period into two cohorts: 2019 (prior to the pandemic and publication) and April 2020–March 2021 (in the midst of the pandemic and following guideline publication). The results of this study will be used to guide future interventions to improve contraception documentation, efficacy and alignment with the ACR guidelines.

METHODS

The RISE registry includes data from approximately 30% of the entire US clinical rheumatology workforce. The data in the RISE registry include structured variables within the EHR, including diagnosis and Current Procedural Terminology (CPT) codes, medication and allergy lists and demographics that providers record during the course of routine clinical care. Study-specific data are not collected.

Study design and patient populations

The two 1-year cohorts studied included the prepandemic cohort (2019) and the mid-pandemic/telehealth cohort (April 2020–March 2021). For each cohort, we included female patients between the ages of 18 and 44 years who had at least one clinic visit documented in the RISE registry in the corresponding study period, that is, 2019 or between 1 April 2020 and 31 March 2021. Each woman was required to have at least two visits with International Classification of Diseases (ICD)-9 or ICD-10 diagnostic codes for SLE (710.0, 710.00 or M32.x (except M32.0)) at least 30 days apart. Patients could be included in both analyses.

Study end points

This study aimed to identify patient, provider and practice characteristics significantly associated with contraception documentation in patients with SLE, and to determine if real-world contraception practices align with the 2020 ACR guidelines.

Contraception documentation

Contraception documentation was ascertained from structured fields within the EHR, including the patient's medication (medication name and National Drug Codes (NDC)), problem and diagnosis (ICD and Systemised Nomenclature of Medicine (SNOMED) codes) and procedure fields (ICD, SNOMED and CPT codes) that included contraceptive information. Our data abstraction methods could not identify free-text documentation that did not appear in a structured field (eg, physician notes). The registry did not include a structured field for contraception. Menopause and surgical sterilisation that occurred by the end of each study period were included. All the other contraceptives were included if there was a record of them during the study period. While LARC can be inserted in the months to years prior to the study period, we restricted documentation of their use to the year of study.

Contraception methods were categorised according to expected real-world efficacy: highly effective (<1% failure rate), effective (4%–9% failure rate), barrier (>15% failure rate), unknown form and other (online supplemental table S1).[14] Patients with two forms of contraception were included in the more-efficacious group if both contraceptives were recorded at a single visit.

Medications

Medication information was extracted from three sources within the registry: (1) patient medication tables, as reported by patients in the medication reconciliation process during a clinical visit; (2) e-prescription tables, which are the electronic medication orders sent from practices to pharmacies; (3) procedure tables, which include CPT codes for procedures that include medication administration.[13] Medications from all three tables are associated with a start date. If available, medication stop dates were based on actual stop dates input into the EHR; if these were not available, stop dates were calculated as 90 days after the last observed medication documentation date.

The teratogenicity of disease-modifying antirheumatic drugs were categorised according to the ACR Reproductive Health Guideline (online supplemental table S2).[12] Patients in the teratogen group had a prescription for any teratogenic disease-modifying antirheumatic drugs (DMARDs); patients in the unknown risk group had a prescription for a medication in this category and women in the pregnancy-compatible group were only prescribed DMARDs that are considered compatible with pregnancy. Patients who were not prescribed a DMARD were included in the pregnancy-compatible group.

Covariates

Patient characteristics

Patient demographics included age (18–20, 21–25, 26–30, 31–35, 36–40 and 41–44 years), race and ethnicity (white, black, Asian, Hispanic, multiracial and unknown), Area Deprivation Index (ADI; an area-level measure of socio-economic status (SES) with a range of 1–100, with lower scores reflecting higher SES), geographic division (Pacific, East North Central, East South Central, Mid-Atlantic, Mountain, New England, South Atlantic, West North Central and West South Central) and insurance type (private, Medicare, Medicaid, other and unknown).[15] We extracted patient clinical characteristics including the number of rheumatology visits during each study period, the Charlson Comorbidity Index (CCI) (based on the Deyo protocol) through the end of each study period, and whether they had at least one visit with an advanced practice practitioner (APP).[16] We also assessed for history of lupus nephritis (LN; yes/no, defined as 1 ICD code of M32.14 or 2 ICD codes of nephritis (580–586, 791.0, N00,

N04, N05, N17, N18 and R80.9, at least 30 days apart)) and high risk for thrombosis. High risk for thrombosis was defined as ever had antiphospholipid syndrome (APS; 1 ICD code of D68.61) by the end of each study period or any anticoagulant use (including warfarin, coumadin, dalteparin, enoxaparin, fondaparinux, argatroban, bivalirudin, heparin, apixaban, rivaroxaban, edoxaban, dabigatran, prasugrel, ticagrelor, clopidogrel, dipyridamole, alteplase and reteplase) during each study period. Visit type was also extracted for the mid-pandemic cohort analysis (all in-person, all telehealth or both). Telehealth visits were identified by CPT codes (99441, 99442, 99443, 98966, 98967 and 98968) and place of service (POS)/modifiers (GQ, GT, 95 and POS 02).[17]

Provider and practice characteristics

Provider characteristics included the gender of patients' most-commonly seen provider (female or male) and whether the provider was an APP (yes/no). Provider age and duration in practice was estimated based on the date that a provider's National Provider Identification (NPI) was assigned: if their NPI was assigned in 2006, when NPI numbers were first assigned, they were included in the 'before 2006' group; if their enumeration date was 2007 onwards, the provider was assigned to 'after 2006' group. Practice characteristics include practice type (health system; multispecialty group practice; single specialty group practice or solo practitioner) and EHR vendor (Allscripts, GE Centricity, NextGen, eClinicalWorks, eMDs and other).

Statistical analysis

Descriptive statistics were reported on both cohorts. We used multilevel logistic regression models that included age, race and ethnicity, ADI (<85 and ≥85), practice type, number of rheumatology visits, history of LN, CCI score (≥2, yes/no), provider gender, provider age, provider APP (yes/no), EHR vendor, high risk for thrombosis (yes/no) and composite medication groups (pregnancy compatible, any teratogen, unknown teratogenicity and no medications) to estimate the association between any contraception documentation and patient and provider characteristics, accounting for clustering by practice. For the mid-pandemic cohort, we adjusted for all the above variables and for visit type (in-person plus telehealth vs all in-person and all telehealth).

We performed additional analyses on the 2019 cohort: (1) in a series of separate models, we assessed the association between contraception documentation and history of LN, high risk for thrombosis, immunosuppression use, mycophenolate or mycophenolic acid use and teratogenic medication use. Unadjusted predicted margins with 95% CIs were reported, as were results that were adjusted for patient age and EHR vendor accounting for clustering by practice; (2) in a series of separate models limited to women with contraception documentation, we assessed the association between highly effective contraception documentation and the same stratified variables listed above. Again, unadjusted predicted margins with CIs were reported, as were results that were adjusted for patient age and EHR vendor accounting for clustering by practice. Analyses were performed using Stata V.15 (StataCorp, College Station, Texas, USA).

RESULTS

Contraception documentation overall

In 2019, 8.2% of women of reproductive age with SLE had contraception documented within the RISE registry. Between April 2020 and March 2021, this documentation increased to 8.5% of women.

Prepandemic: January–December 2019

A total of 11 676 women with SLE had at least one visit in a RISE registry practice in 2019. They were seen by 1057 clinicians across 218 practices. In models adjusted for all patient, provider and health system variables, the only patient characteristics that correlated with contraception documentation were race, age and the number of visits within the year (table 1). Young women, especially those aged 18–20 years, had higher rates of contraception documentation, with a rate of 15.6% (95% CI 11.4 to 19.7). Women aged 18–30 years had significantly higher rates of documentation compared with women aged 31–44 years. Non-Hispanic white women had significantly higher rates of contraception documentation than Asian, black and Hispanic women. In the results from the multivariate model, several patient characteristics did not independently correlate with contraception documentation. These included residence in a neighbourhood with a high 'ADI', a history of LN, high risk for thrombosis and a higher score on the CCI. Documentation of contraception was not significantly higher among women prescribed teratogens compared with those only prescribed pregnancy-compatible medications.

Practice characteristics were the primary predictors of contraception documentation when adjusted for patient demographics, medication teratogenicity, provider and practice characteristics (table 2). An adjusted 23.4% of women cared for within health systems had contraception documentation, compared with 6.5%–8.9% of women in solo, single-specialty and multispecialty practices. The EHR vendor also played a large role, with 21.9% of women cared for within Allscripts and 15.2% within eClinicalWorks having contraception documented, but only 6.4% within NextGen, which is the most commonly used EHR within the RISE registry.

The region of the country in which the patients received care impacted contraception documentation, with the lowest rates of documentation in the Pacific, Mid-Atlantic and Mountain regions. Male rheumatologists were modestly less likely to document contraception than female rheumatologists (7.7% vs 8.8%, p<0.05). On the other hand, the provider duration in practice did not correlate with contraception documentation. The frequency of contraception documentation was similar

Table 1 Contraception documentation based on patient characteristics in the prepandemic and mid-pandemic periods

	Prepandemic: 2019			Mid-pandemic: April 2020–March 2021		
	Number of women	Percentage with contraception documented	Adjusted analysis predicted margins (95% CI)	Number of women	Percentage with contraception documented	Adjusted analysis predicted margins (95% CI)
Women with SLE aged 18–44 years	11676	8.2%	N=11 670*	9763	8.5%	N=9732†
Patient characteristics						
Age (years)						
18–20—ref	367	15.3	15.6 (11.4 to 19.7)	189	19.0	19.4 (14.3 to 24.4)
21–25	1087	12.6	12.7 (10.3 to 15.1)	861	15.7	15.8 (13.2 to 18.4)
26–30	1721	10.6	10.8 (9.3 to 12.3)‡	1457	11.1	11.5 (9.6 to 13.3)
31–35	2400	7.7	7.6 (6.5 to 8.7)	2024	7.7	8.0 (6.8 to 9.3)
36–40	3111	6.8	6.7 (5.7 to 7.7)	2653	6.9	7.1 (5.9 to 8.2)
41–44	2990	6.4	6.3 (5.3 to 7.2)	2579	6.2	6.4 (5.4 to 7.4)
Race and ethnicity						
Asian	469	6.4	6.4 (4.4 to 8.4)	383	6.3	7.8 (6.3 to 9.3)
Black	2528	7.7	6.4 (5.4 to 7.3)	2041	8.8	6.7 (4.9 to 8.6)
Hispanic	1494	6.0	6.2 (5.0 to 7.5)	1227	6.2	5.9 (3.5 to 8.3)
Multiracial/Other	85	8.6	8.6 (1.9 to 15.2)	75	9.3	10.1 (2.9 to 17.3)
Unknown	1952	7.2	8.5 (7.2 to 9.9)	1819	7.6	10.2 (8.9 to 11.4)
White—ref	5148	9.7	9.9 (8.8 to 11.0)	4218	9.6	8.7 (7.2 to 10.2)
ADI						
<85—ref	9431	8.2	8.3 (7.6 to 9.1)	7972	8.2	8.7 (7.7 to 9.6)
≥85	1117	6.7	7.0 (5.6 to 8.4)	910	8.1	8.2 (6.4 to 10.1)
Unknown	1128	10.1	8.4 (6.1 to 10.6)	881	11.4	10 (7.2 to 12.9)
Insurance‡						
Medicaid	1068	7.0	–	924	8.8	–
Medicare	1035	8.7	–	760	8.6	–
Other	577	6.9	–	475	5.7	–
Private	7556	8.6	–	6409	8.9	–
Unknown	1440	7.2	–	1195	7.5	–
Clinical characteristics						
History of lupus nephritis						
No—ref	9846	8.0	8.2 (7.5 to 9.0)	8092	7.9	8.4 (7.5 to 9.2)
Yes	1830	9.5	8.0 (6.5 to 9.4)	1671	11.5	10.3 (8.5 to 12.1)
High risk for thrombosis						
No—ref	10799	8.2	8.3 (7.6 to 9.0)	8995	8.4	8.8 (8 to 9.6)
Yes	897	9.0	7.5 (4.7 to 10.3)	768	9.9	8.3 (5.7 to 10.9)
Charlson Comorbidity Index score ≥2						
No—ref	9806	8.0	8.1 (7.4 to 8.8)	8298	8.3	8.6 (7.8 to 9.5)
Yes	1870	9.5	8.9 (7.1 to 10.6)	1465	9.8	9.4 (7.9 to 10.9)
Medication						
Only pregnancy-compatible	7344	8.0	8.4 (7.5 to 9.2)	6233	7.6	8.4 (7.3 to 9.5)
Any teratogen	2527	10.5	9.0 (7.9 to 10.2)	2557	10.1	9.1 (7.9 to 10.3)
Unknown teratogenic risk	1027	9.2	8.6 (6.8 to 10.3)	942	10.3	9.9 (8 to 11.7)
None of the above	778	1.9	2.2 (1.1 to 3.3)	31	0.0	–§

*In the prepandemic period, none of the patients with a Charlson Comorbidity Index score of 0 (n=6) had documentation, so were excluded from the adjusted analysis.
†In the mid-pandemic period, none of the patients in 'none of the above' medication group (n=31) had documentation of contraception, so were excluded from the adjusted analysis.
‡Insurance was not included in the adjusted model because it was co-linear with the ADI and included more missing data than the ADI.
§Fewer than 10 women had documentation of contraception, precluding further analysis.
ADI, Area Deprivation Index; ref, reference.

Table 2 Contraception documentation based on provider and practice characteristics in the prepandemic and mid-pandemic periods

	Prepandemic: 2019			Mid-pandemic: April 2020–March 2021		
	Number of women	Percentage with contraception documented	Adjusted analysis predicted margins (95% CI)	Number of women	Percentage with contraception documented	Adjusted analysis predicted margins (95% CI)
Practice characteristics						
Practice type						
Health system—ref	403	15.9	23.4 (13.2 to 33.6)	228	18.4	17.5 (6.5 to 28.4)
Multispecialty group practice	1345	9.9	8.9 (6.2 to 11.6)	1126	9.9	8.9 (5.7 to 12.1)
Single-specialty group practice	8164	8.2	7.9 (6.9 to 8.9)	6964	8.7	8.9 (7.7 to 10)
Solo practitioner	1764	5.5	6.5 (5.0 to 8.0)	1445	5.0	6.3 (4.5 to 8)
Electronic health record vendor						
Allscripts—ref	340	22.1	21.9 (13.6 to 30.3)	302	17.9	20.3 (9.7 to 31)
eClinicalWorks	1797	14.7	15.2 (13 to 17.3)	1534	16.1	16.7 (14.2 to 19.2)
eMDs	786	5.7	7.9 (2.2 to 13.6)	119	10.9	13 (0 to 33.3)
GE Centricity	653	6.7	8.4 (6.5 to 10.4)	534	7.7	9.4 (6.4 to 12.3)
NextGen	6204	6.4	6.4 (5.5 to 7.2)	5217	6.5	6.5 (5.5 to 7.6)
Other	1896	7.0	5.6 (3.8 to 7.5)	2057	6.8	6.4 (4.2 to 8.5)
Visit type						
All in-person		–	–	6763	9.0	8.9 (7.9 to 9.8)
All virtual		–	–	335	6.9	9.7 (7.2 to 12.1)
Mix of virtual and in-person—ref		–	–	2665	7.5	8.4 (7.1 to 9.6)
Region						
East North Central	956	9.4	7.3 (5.6 to 9.1)	815	9.6	7.9 (5.5 to 10.3)
East South Central	1216	8.7	9.5 (7.6 to 11.5)	1056	9.5	9.7 (6.4 to 13)
Mid-Atlantic	1264	4.4	5.3 (3.4 to 7.1)	966	4.6	5.9 (4.3 to 7.6)
Mountain	684	5.8	6.3 (4.6 to 8.0)	612	7.8	6.9 (4.7 to 9.2)
New England	229	14.4	16.6 (6.6 to 26.5)	220	13.6	18 (4.5 to 31.5)
Pacific—ref	1200	3.8	5.3 (3.4 to 7.2)	994	3.8	5.1 (2.7 to 7.4)
South Atlantic	3800	8.5	9.1 (7.5 to 10.7)	3194	8.0	9 (7.4 to 10.7)
West North Central	849	9.8	10.3 (7.0 to 13.7)	749	10.1	11.6 (7.4 to 15.8)
West South Central	1478	12.6	8.1 (6.2 to 10.1)	1157	13.8	9.8 (7.7 to 11.9)
Provider characteristics						
Gender of the most-seen provider						
Female—ref	5297	9.2	8.8 (8.0 to 9.6)	4433	9.7	9.5 (8.3 to 10.6)
Male	6379	7.4	7.7 (6.8 to 8.6)	5330	7.6	8.1 (7.2 to 9.1)
Provider started in practice						
Before 2006—ref	7276	7.9	8.6 (7.8 to 9.5)	5992	8.0	9 (8 to 10.1)
After 2006	4400	8.8	7.6 (6.5 to 8.6)	3771	9.3	8.4 (7.2 to 9.5)
Most frequent provider-type in the year						
Most visits with physician	2162	8.2	8.1 (7.4 to 8.8)	1813	8.6	8.8 (7.9 to 9.7)
Most visits with APP	1286	8.4	8.8 (6.9 to 10.8)	1102	7.8	8.3 (6.4 to 10.2)

APP, advanced practice practitioner; ref, reference.

for patients who predominantly saw a physician or an advanced practice provider within the rheumatology clinic.

Mid-pandemic: April 2020–March 2021

A total of 9763 women with SLE had at least one visit in a RISE registry practice during this mid-pandemic period seen by 1045 clinicians in 212 practices. Of these, 6763 women only had in-person visits, 335 (3.4%) women only had virtual visits and 2665 (27.4%) had a combination of visit types. In adjusted modelling, there was no significant difference in contraception documentation in women seen between in-person and telehealth visits.

In the mid-pandemic period, age, race and increased visits in the year remained the primary patient characteristics associated with contraception documentation. Again, women under 30 years had higher rates of documentation than women over 30 years and non-Hispanic white women had significantly higher rates of contraception documentation. Unlike in 2019, in this time period, more women with than without a history of LN had contraception documentation. Despite this difference, there remained no significant difference in contraception documentation based on the prescription of teratogenic medications.

In the mid-pandemic period, the higher rate of contraception documentation found in health systems was somewhat lower than prepandemic (17.5%, 95% CI 6.5 to 28.4). The Allscripts and eClinicalWorks EHR systems still had the highest frequency of documentation with NextGen reporting the lowest rate. Differences in contraception documentation persisted based on the region of the country where the clinic was located. Additionally, male providers were less likely to document contraception. However, the duration in practice and training of the rheumatology provider again did not correlate with contraception documentation.

When adjusted for the woman's age and the provider's EHR and clustering by practice, the rate of contraception documentation was similar in these two periods (prepandemic 8.2% vs mid-pandemic 8.6%, p=0.24; table 3). Among the women with contraception documentation, the frequency of highly effective contraception, which includes menopause and surgical sterilisation, was similar (prepandemic 32.4% vs mid-pandemic 34.8%, p=0.16). Additionally, the frequency of LARC (IUD or implant) use was similar in these two periods when excluding women with surgical sterilisation or menopause (prepandemic 18.1% vs 21.4% mid-pandemic, p=0.11).

Alignment of contraception use with the ACR reproductive health guidelines

We assessed the contraceptives prescribed to subgroups of women with SLE in 2019 to determine baseline alignment with the ACR guidelines, which were published in early 2020. All of the women included in this analysis had documentation of contraception in 2019 and were not

Table 3 Contraception documentation and effectiveness among high-risk subgroups of women with SLE in 2019

		Contraception documentation			Highly effective contraception Includes surgical sterilisation, menopause, IUD and implant among patients with contraception documentation		
	Total patients, n	Patients with contraception documented, n (%)	Predictive margins*, % (95% CI)	P value†	Patients with highly effective contraception, n (%)	Predictive margins*, % (95% CI)	P value†
Timing of visit							
Prepandemic	11676	961 (8.2)	8.2 (7.7 to 8.7)		315 (32.8)	32.4 (29.6 to 35.2)	
Mid-pandemic	9763	831 (8.5)	8.6 (8 to 9.1)	0.24	286 (34.4)	34.8 (31.7 to 37.9)	0.16
High risk for thrombosis							
No	10799	880 (8.2)	8.2 (7.4 to 9.0)		263 (29.9)	30.6 (26.8 to 34.3)	
Yes	897	81 (9.0)	7.4 (4.4 to 10.3)	0.57	52 (64.2)	49.3 (39.9 to 58.7)	<0.001
Lupus nephritis							
No	9846	788 (8.0)	8.2 (7.3 to 9.1)		233 (29.6)	29.2 (25.6 to 32.9)	
Yes	1830	173 (9.5)	7.7 (6.1 to 9.2)	0.49	82 (47.4)	45.8 (39.3 to 52.4)	<0.001
Immunosuppression							
No	5748	372 (6.5)	7 (6.2 to 7.8)		118 (31.7)	31.2 (26 to 36.3)	
Yes	5928	589 (9.9)	9.1 (8 to 10.2)	<0.001	197 (33.4)	32.2 (28.1 to 36.3)	0.70
Mycophenolate or mycophenolic acid							
No	10221	812 (7.9)	8.1 (7.2 to 9)		260 (32.0)	30.7 (26.9 to 34.5)	
Yes	1455	149 (10.2)	8.3 (7 to 9.6)	0.78	55 (36.9)	37.9 (31.0 to 44.7)	0.03
Teratogenicity of rheumatic medications							
Pregnancy compatible (ref)	7344	586 (8.0)	8.1 (7.1 to 9.1)		169 (28.8)	27.4 (23.2 to 31.5)	
Teratogen	2527	266 (10.5)	9.3 (8 to 10.6)	0.06	91 (34.2)	33.2 (27 to 39.4)	0.06
Unknown teratogen risk	1027	94 (9.2)	9.4 (7.5 to 11.3)	0.13	40 (42.6)	40 (30.5 to 49.5)	0.01

*GEE model adjusting for age and EHR, clustering by practice.
†p-value from chi-square.
EHR, electronic health record; IUD, intrauterine device.

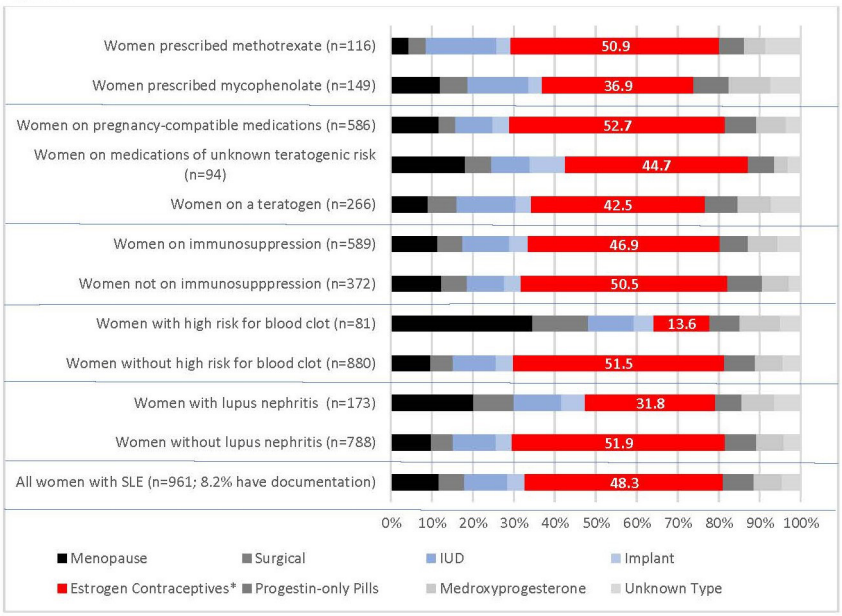

Figure 2 Contraceptive effectiveness among women with SLE with documented contraception, categorised by the teratogenicity of their rheumatic medications and other risk factors for contraceptive use. The red bar indicates the percentage of women using an oestrogen-containing contraception*, which includes oestrogen-progesterone pills, patch and ring. IUD, intrauterine device; LN, lupus nephritis; MMF, mycophenolate mofetil; MTX, methotrexate.

documented to have menopause or surgical sterilisation. Alignment with the 2020 ACR reproductive guidelines, when adjusted for age of the patient and the type of EHR, varied by recommendation and group (figure 2, table 4):

- The guidelines recommend against using the oestrogen patch. Only 14 women with SLE had documentation of the oestrogen patch, which represents 0.1% of all patients with SLE and 1.5% of those with contraception documentation.
- Emergency contraception is recommended as safe for all women with rheumatic disease and was documented in 2.6% of women with SLE, 6% among women prescribed a teratogen compared with 1.5% for women on pregnancy-compatible medications (p<0.001).
- Among women with an increased risk for thrombosis, indicated in this analysis by a diagnosis of APS or current use of anticoagulation, the guidelines recommend against oestrogen, encourage the IUD or progesterone-only pills and discourage use of medroxyprogesterone. In the RISE registry, women at high risk for thrombosis were more likely to be prescribed progesterone-only contraceptives, including the IUD (21.4% with thrombotic risk vs 12.5% without), progesterone-only pills (14.3% with thrombotic risk vs 8.8% without) and medroxyprogesterone (19.1% with thrombotic risk vs 7.9% without). Oestrogen-containing contraceptives were reported significantly less frequently in women with thrombotic risk (26.2%) vs women without thrombotic risk (60.6, p<0.0001).
- For women with moderate-to-severe SLE activity, the guidelines recommend avoiding oestrogen and encourage IUD, progesterone pills and progestin implants. Unfortunately, SLE activity is not systematically recorded within the RISE registry. We used history of LN as a proxy for a history of highly active SLE. Women with a history of LN were less likely to use an oestrogen-containing contraception (63.2% without a history of LN vs 53.8% with a history of LN, p=0.024) and more likely to use an IUD or the progesterone-only pill (35.8% without a history of LN vs 45.3% with a history of LN, p=0.047).
- The guidelines recommend that the IUD is safe for women on immunosuppression; documentation of the IUD was similar between women with and without immunosuppression.
- The guidelines recommend IUD or double contraception for women on MMF. In the RISE registry, IUD use was not significantly higher among women on MMF than off this medication (12.1% off MMF vs 17.4% on MMF, p=0.08). Barrier methods and double contraceptives were not identified within RISE.
- While the guidelines do not specifically recommend contraception for women on a teratogen, it is standard practice to recommend highly effective contraception to limit birth defects. In the RISE registry, use of the IUD or progestin implant was not significantly higher in women prescribed a teratogen (15.3% on pregnancy-compatible medications, 20.5% on a teratogen, p=0.07), although it was for women on medications of unknown teratogenicity (15.3% on pregnancy-compatible medications, 25.4% on a medication of unknown teratogenic risk, p=0.02).

Table 4 Alignment of ACR recommendations for contraception in patients with SLE with current documented contraception practices

ACR contraception recommendations	Current contraception practices documented within the RISE registry
All patients with SLE of childbearing age	
► Discuss contraception and pregnancy plans at initial or early visit and when initiating potentially teratogenic medications (GPS).	► Low adherence suggested by the overall rate of contraception documentation.
► Counselling regarding contraceptive methods based on efficacy, safety and individual patient values/preferences (GPS).	► Full adherence not expected due to patient autonomy in reproductive health decisions.
► Use barrier methods over less effective or no contraception, where other more effective forms are contraindicated (GPS).	► Barrier methods was not documented within the RISE registry during this period.
► Avoid the oestrogen patch (GS2B).	► Used by 1.5% of women with documented contraception.
► Use emergency (postcoital) contraception when necessary (GS6).	► Used by 6% of women on a teratogen with documented contraception.
Increased thrombotic risk *APS and current anticoagulation is used a proxy for women at increased risk for thrombosis*	
► Avoid oestrogen-progestin contraceptives (GS3).	► Lower use of oestrogen-containing contraceptives in women with increased thrombotic risk.
► Use IUDs (copper or progestin) or a progestin-only pill over other hormonal contraceptives (GS4).	► Modest increase in IUD and progesterone-only use in women with increased thrombotic risk.
► Avoid depot medroxyprogesterone.	► Higher use of depot medroxyprogesterone in women with increased thrombotic risk.
SLE disease activity (aPL negative) *A history of LN is used as a proxy for women with moderate-to-severe SLE activity*	
Low SLE activity	
► Use oestrogen-progestin pill, vaginal ring, progestin-only contraceptives or IUDs over less effective or no contraception (GS2).	► Low rates of documentation of effective contraception.
► Conditionally recommend IUDs and progestin implant over other hormonal contraceptives (GS2A).	► Low rates of LARC or progestin implants.
Moderate-to-severe SLE activity (including LN)	► Unable to identify current SLE activity with RISE registry.
► Avoid oestrogen-progestin contraception (GS2C).	► Less oestrogen-based contraceptive and more progestin-only contraceptive use among patients with a history of LN.
► Use progestin-only or IUD contraceptives.	► No increase in IUD or implant with a history of LN.
Medication-based recommendations	
Immunosuppressive therapy	
► Use an IUD (copper or progestin) as an appropriate contraceptive when desired (GS7).	► Similar rates of IUD in patients with and without immunosuppression.
Mycophenolate mofetil or mycophenolic acid	
► For reversible contraception, conditionally recommend an IUD (alone) or two forms of alternative contraception (GS11).	► Similar rates of IUD use in patients with and without MMF. ► Barrier methods are not documented within the RISE registry.
Teratogenic medications	► Modestly higher frequency of contraception documentation, highly effective contraception and LARC
	► Higher use of emergency contraception.
Medications of unknown teratogenic risk	► No increase in contraception documentation. ► Higher use of highly effective contraception and LARC.

ACR, American College of Rheumatology; aPL, antiphospholipid antibodies; APS, antiphospholipid syndrome; GPS, good practice statement; GS, guideline statement; IUD, intrauterine device; LARC, long-acting reversible contraception; LN, lupus nephritis; MMF, mycophenolate mofetil.

DISCUSSION

This study of the RISE registry demonstrated large gaps in contraception documentation for patients with SLE and partial alignment of current contraception patterns with the 2020 ACR guidelines. Given the pivotal role of contraception for pregnancy planning among patients with SLE, improving procedures for contraception data collection and enhancing the use of appropriate contraception is critical.

Contraception practices were not impacted by the COVID-19 pandemic, with comparable rates of documentation and similar independent predictors identified

in both the prepandemic and mid-pandemic groups. Telehealth-based care contributed to this consistency with similar rates of contraception documentation for in-person and telehealth visits. While evidence to support the use of telehealth care in SLE is limited, So *et al*[18] recently showed that patients with high SLE activity who were treated via telehealth during the pandemic experienced similar disease control when compared with those treated with standard care.

The most significant factors associated with contraception documentation were the EHR vendor and the type of practice, suggesting that the ease of documentation is a key driver of documentation. Rheumatology practices within a health system had significantly higher rates of contraception documentation, perhaps driven by contraception information documented in the EHR in visits outside of the rheumatology clinic.

Patient race was a strong predictor of contraception documentation, with the highest rates observed for white patients. This may reflect racial and ethnic disparities in patterns of contraception usage. Despite higher pregnancy complications among black and Hispanic patients, studies have shown that white patients more often use contraception and highly effective contraceptive methods.[19 20] Among women with SLE, while black and Hispanic women with Medicaid insurance have more encounters for contraceptive care, they are less likely to obtain highly effective contraception.[19] Qualitative studies suggest that mistrust of the health system among black and Hispanic patients may contribute, as these patients experience more implicit pressure to accept provider recommendations despite receiving inadequate risk information, which leads to less patient autonomy and potentially increasing discontinuation of contraception.[21 22] Higher documentation rates were also associated with younger age, possibly due to age-related differences in preferred contraceptive methods. Patients aged 20–29 years are most likely to use contraceptive pills, which can be documented in the 'medications list' field in the RISE registry. In contrast, patients aged 30–39 years more often use surgical contraception and LARC, which are less likely to be listed within the available fields.[23] These results highlight the need for improved patient-centred contraception care and standardised procedures for recording contraceptive information.

The contraception practices in 2019 were partially aligned with the 2020 ACR reproductive health guidelines. Women in the RISE registry at high risk for thrombosis and a history of LN receive fewer oestrogen-containing contraceptives than lower risk women, aligned the guidance from the ACR. The oestrogen patch, which provides a higher daily dose of oestrogen than other contraceptives, is very rarely prescribed to women with SLE.[24] As randomised trials have demonstrated the relative safety of oestrogen-containing contraceptives for women with mild and stable SLE, it is appropriate that over 50% of lower risk women with SLE in the RISE registry with contraception documentation receive these well-tolerated and effective options.[25–27]

Although the ACR reproductive health guidelines recommend LARC, such as the IUD and progestin implant, for women at high risk for pregnancy complications—including women with moderate-to-severe SLE, on immunosuppression and on mycophenolate—none of these groups were more likely to have documentation of LARC. In conflict with the ACR guidelines, significantly more patients using anticoagulation were using medroxyprogesterone compared with those without anticoagulation. While depot medroxyprogesterone has historically been considered lower-risk for thrombosis, contradictory data have been published in recent years casting this assumption in doubt.[28–31]

Teratogenic therapies necessitate the use of effective contraception to prevent medication-related fetal anomalies. In alignment with the Food and Drug Administration's Risk Evaluation and Mitigation Strategy (REMS) recommendations, the ACR specifies that women receiving MMF use either an IUD or combination of two contraceptives due to its potential impact on the efficacy of oral hormonal contraceptives.[32] Just as found in this study, previous studies have demonstrated that, while there is a lack of correlation between the use of teratogens and any contraception, the contraceptives used by women taking a teratogen are more often highly effective.[10 19] Quinzanos *et al*, reported large gaps in teratogen education with over 50% of patients using medications with teratogenic risk receiving no counselling regarding potential risk.[33]

This study has several limitations. Contraception documentation does not necessarily indicate contraception use. Because the RISE registry is currently not able to search broadly in clinic notes for detailed information, only contraception documented within a discrete field in the EHR was available at this time for analysis. Additionally, some patients may use contraception of which their rheumatologists are unaware, while others may have documentation for contraceptives that they no longer used. Despite this, the rate of contraception documentation is very similar for women in the RISE registry to the rate of contraception use for women with SLE in the Medicaid population, where data about contraception dispensing and insertion are more consistent.[19] We had to use proxy populations to assess alignment of contraception use with the ACR guidelines because few patients within the RISE registry have measures of SLE activity or the results of aPL antibodies. Large gaps in documentation limit the power to assess differences between subgroups of patients. As the RISE registry currently includes >17 million visits for >2 million patients, however, the impact of missing data may overcome by the large dataset. Demonstrating this point, we found significant differences in women with a history of LN, on anticoagulation and based on the teratogenicity of medications.

An important goal of this study was to identify opportunities to enhance contraceptive care within rheumatology

practices. Based on the importance of the type of clinic and EHR in contraceptive documentation, we anticipate that clinic-level interventions that are designed to enhance the ease of documentation within a clinic visit may be effective. We have already begun this work, partnering with several rheumatology offices on the NextGen EHR system that contribute to the RISE registry, to implement simple approaches for contraceptive documentation that both collect important data and enable the rheumatologist to appropriately address contraceptive needs with the patient. Additionally, several groups have developed evidence-based best practices for ascertaining pregnancy intention, including using the One Key Question ("Would you like to become pregnant in the next year?") and a set of three PATH (Pregnancy Attitudes, Timing and How important is pregnancy prevention) questions.[34–36] These open-ended questions allow women to share their interest in pregnancy, allowing the provider to effectively counsel about both pregnancy and contraception, as appropriate to the patient. Adding such an approach to routine rheumatology care could be an effective strategy to improve pregnancy timing and outcomes.[37]

A secondary goal of this study was to identify specific patient and/or provider populations that would benefit from enhanced contraceptive care. Our results suggest that rheumatology providers — whether male or female, younger or older, physician-trained or advanced-practice providers — all document contraception fairly similarly. About one in three young women in the RISE registry had at least one visit with an APP, suggesting that augmenting the roles of these providers, many of whom are young women, may be an effective strategy to improve ACR-aligned care.[38] We again found that women of colour may be receiving disproportionately less reproductive care within rheumatology practices. Targeted programmes may be needed to address disparities, especially among patients of colour.[39 40] In addition, the slightly higher rates of contraceptive use and use of LARC among women prescribed a teratogen suggest that this is a particularly high-need patient population.

The publication of the ACR reproductive health guidelines, coupled with the recent changes in abortion law, provides an opportunity to change contraceptive care for women with SLE.[41] Contraception documentation has the potential to serve as an important quality measure among women of reproductive age with rheumatic disease. As rheumatologists are often the main physician caring for a woman with SLE of reproductive age, they play a unique role in helping women make decisions about and gaining access to contraception. The RISE registry data suggest that there is significant room for improvement in documenting contraception, and in ensuring that rheumatologists and women understand the range of safe contraceptive options that are available.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study was approved by Western IRB (WIRB) and the UCSF Committee on Human Research (WIRB Work Order number for RISE is #1-797516-1). The RISE registry is a shared resource sponsored by the American College of Rheumatology (ACR). The ACR has received the necessary approvals and exemptions from the WIRB for the procedures for collecting the data in the RISE registry and using it for research purposes. Access to the primary data is restricted to the Data Analytic Centers based at UCSF and the University of Alabama, Birmingham to ensure effective stewardship of the data. Each data analytic center (DAC) has also received IRB approval from their local institutions to conduct analyses of the data. Investigators may request analysis of data by applying to and gaining approval from the ACR Research & Publications Subcommittee.

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