Award Number: W81XWH-20-1-0692

TITLE: EHR-Based Longitudinal Cohort to Explore Pregnancy Outcomes in SLE (ELIPTCL)

PRINCIPAL INVESTIGATOR: Dr. Rosalind Ramsey-Goldman, MD, PrPH

CONTRACTING ORGANIZATION: Northwestern University

REPORT DATE: OCTOBER 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
OCTOBER 2023	Annual	1SEPT2022 - 31AUG2023

4. TITLE AND SUBTITLE

EHR-Based Longitudinal Cohort to Explore Pregnancy Outcomes in SLE (ELIPTCL)

5a. CONTRACT NUMBER
W81XWH-20-1-0692

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Systemic Lupus Erythematosus (SLE) is an archetypical autoimmune disease with protean manifestations leading to excessive morbidity and mortality especially as it relates to pregnancy outcomes. Half of all lupus pregnancies result in a loss, preterm birth, and/or preeclampsia, increasing the likelihood of permanent disability to both mother and child. We hypothesize that pregnancies managed according to the ACR Guidelines will have improved maternal, pregnancy, or infant morbidity. ACR-aligned care includes appropriate preconception counseling, pregnancy timed to coincide with quiet disease, pregnancy-compatible medications continued and teratogens stopped preconception, and timely management by rheumatologists and Maternal-Fetal Medicine. The overarching objectives of this proposal are to use Electronic Health Record (EHR)-based tools in the Chicago Area Patient-Centered Outcomes Research Network, CAPriCORN, the Patient-Centered Outcomes Research Network (PCORnet) site in Chicago to describe occurrence and predictors of heterogeneous pregnancy outcomes in maternal SLE across multiple sites, and to assess the impact of ACR guideline-guided care in maternal lupus using real-world data collected at the point of care as the foundation for study evaluation. Women make up a significant proportion of our armed forces and veterans in the US and the active duty female force is racially diverse. Approximately 50% of those women are in their childbearing years and who will need management of reproductive issues.

15. SUBJECT TERMS

NONE LISTED

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRDC
U	U	U	UU	21	**19b. TELEPHONE NUMBER** *(include area code)*

Table of Contents

1. INTRODUCTION

Systemic Lupus Erythematosus (SLE) is an archetypical autoimmune disease with protean manifestations leading to excessive morbidity and mortality especially as it relates to pregnancy outcomes. Preliminary work by our team includes using electronic health record (EHR)-based tools to identify SLE, reproductive outcomes, risk factors for disease severity, and outcomes for lupus and lupus nephritis. The ELIPTCL team will apply these tools in the Chicago Area Patient-Centered Outcomes Research Network, CAPriCORN, a Patient-Centered Outcomes Research Network (PCORnet) clinical data research network, which spans a broad and diverse range of clinical settings in the Chicago metropolitan area including county and academic medical centers and federally qualified health centers. Preliminary data from our collaborators demonstrated that of 146 lupus pregnancies delivered at major University hospitals in the Southeast, 5% resulted in a still birth, 42% in a preterm birth, and 24% had preeclampsia. The primary predictor of these adverse outcomes is active SLE, especially nephritis, during pregnancy. The American College of Rheumatology (ACR) is poised to publish a set of reproductive health guidelines, defining appropriate care for lupus pregnancies. *We hypothesize that pregnancies managed according to the ACR Guidelines will have improved maternal, pregnancy, or infant morbidity.* ACR-aligned care includes appropriate preconception counseling, pregnancy timed to coincide with quiet disease, pregnancy-compatible medications continued, teratogens stopped preconception, and timely management by rheumatologists and Maternal-Fetal Medicine specialists.

The overarching objectives of this proposal are to use EHR-based tools to describe occurrence and predictors of heterogeneous pregnancy outcomes in maternal SLE across multiple sites, and to assess the impact of ACR guideline-guided care in maternal lupus using real-world data collected at the point of care as the foundation for study evaluation. Our aims are 1) Use EHR-based tools to correlate adverse maternal outcomes (lupus nephritis, LN), pregnancy outcomes (preterm birth and preeclampsia), and infant outcomes (low birth weight and intensive care unit admissions) with maternal demographics, lupus disease activity, and pre-existing conditions, and 2) Within sites participating in CAPriCORN, compare the maternal, pregnancy, and infant outcomes for pregnancies managed with and without ACR-Guideline aligned care.

2. KEY WORDS

Systemic lupus erythematosus (SLE), lupus nephritis (LN), pregnancy, electronic health record (EHR), Northwestern Medicine Enterprise Data Warehouse (NMEDW), real world data (RWD), point of care (POC), common data model (CDM), guidelines.

3. ACCOMPLISHMENTS

The table below summarizes the status of work to date including accomplishments and challenges.

Table 1. Update on Workplan

Specific Aim/Task	Progress

Specific Aim 1. Use EHR-based tools to correlate adverse maternal outcomes, pregnancy outcomes, and infant outcomes with maternal demographics, lupus disease activity, & pre-existing conditions	Funded commenced September 2020 and progress impacted by COVID pandemic, all tasks taking longer than expected with remote working conditions, staffing changes, approximately 6-month delays across the board
Task 1. Preparation and Administration	
Establish Steering Committee	Met with each of the partnering PIs during the year to update on study to maximize efficiency because all in person scientific meetings were cancelled
IRB Review and Approval	Contacted Initiating Site PI's IRB and HRPO to establish that Northwestern will be the IRB of record as a single site; protocol and IRB approval from Northwestern (10/7/20) and then HRPO (1/29/21)
Steering Committee and Workgroup meetings with partnering sites	Met with each of the partnering PIs to update on study and incorporate their expertise (see task 2)
Task 2. Implementation and Data Collection	
Develop and Validate Cohort Identification Algorithm (Vanderbilt)	Met with Dr. Barnado virtually to review cohort algorithm, correspondence by email, review of recent literature for updates; initial implementation of cohort identification strategy has been assessed over Northwestern Medicine data warehouse
Develop and Validate Pregnancy Algorithm (Duke)	Met with Drs. Clowse and Eudy virtually to review pregnancy coding for algorithms, correspondence by email, review of recent literature for updates; initial implementation of cohort identification strategy has been assessed over Northwestern Medicine data warehouse
Develop & Validate Lupus Nephritis Algorithm (MUSC, UNC)	Met with Dr. Oates and Dr. Sheikh virtually to review coding for algorithms; correspondence by email, review of recent literature updates; initial implementation of cohort identification strategy has been assessed over Northwestern Medicine data warehouse
Validate datasets via chart review; refine algorithms	In progress at month 24, completed month 28
Query run across CAPriCORN; Project team reviews data; performs preliminary analysis; algorithm refinements based on data analysis; CAPriCORN query update to reflect refinements and rerun final query	Validation of algorithms using Northwestern Medicine data warehouse completed month 30; IRB approval for query run across CAPriCORN completed from ChairB (CAPriCORN) and HRPO month 39. Query run across CAPriCORN anticipated to start month 40
Task 3. Evaluation and Analysis of Data	
Outcomes analysis	Delayed, anticipated start month 42
Task 4. Dissemination and Closeout	
Manuscript preparation	Planned for in year 4
Present at professional meetings	Planned for in year 4 pending meeting schedules
Specific Aim 2: Within CAPriCORN database, compare maternal, pregnancy, and infant outcomes for pregnancies managed with and without ACR-Guideline aligned care	CAPriCORN related activities will start in year 4, validation of algorithms on Northwestern Medicine Datawarehouse and adaption to the PCORnet CDM and testing on the Northwestern Medicine PCORnet CDM Datamart.
Task 1. Implementation and Data Collection	

Update algorithm to add ACR-guideline aligned care	To be done in parallel with development of pregnancy algorithm for aim 1. Validated in Northwestern Dataset, completed month 30.
Validate updated algorithm with ACR-guideline aligned care	Done in parallel with validation of query for aim 1. Validated in Northwestern Dataset. Completed month 30.
Validate datasets via chart review; refine algorithm	Done in parallel with validation of datasets. Completed in month 30.
Query run: data returned	To be done in parallel with validation of datasets. Completed in month 30.
Project team reviews data; performs analysis	See above
Algorithm refinements based on data analysis	See above
CAPriCORN query that reflects local site adjudication and validation	See above – to be run in conjunction with CAPriCORN query described in Task 2 under Aim 1
Query re-run across CAPriCORN; data returned	Omitted. Will not perform due to COVID delays.
Task 2. Evaluation and Analysis of Data	
Outcomes analysis	To be done in parallel with outcomes analysis for aim 1.
Task 3. Dissemination and Closeout	
Manuscript preparation	Planned for year 4
Present at professional meetings	Planned for year 4 but also pending meeting schedules

Updated Data Tables from NMEDW SLE, pregnancy and LN

The data extracted from the NMEDW to test the retrieval of 3 algorithms to detect the SLE phenotype are summarized in Tables 1-4. Patients with SLE were detected in NMEDW using 3 phenotypes (columns 1-3 in Tables 1-4) from Barnardo A, et al. 2017. doi: 10.1002/acr.22989 . All data retrieved from the NMEDW occurred during or after 2007.

The algorithms to detect pregnancy delivery types reported in Tables 3 and 4 used algorithms defined by Barnado A, et al., 2022, DOI: 10.1002/acr.24522

During the validation exercise (see next section), we included the other Barnado phenotype (columns 4 and 5, Tables 1-4) after we realized some patients did not have any data during manual review. Thus, the retrieval of SLE phenotypes was expanded to include two additional Barnado algorithms for the SLE phenotype data extraction.

Table 1. Clinical and Demographic Characteristics of All Patients from EDW

	≥1 SLE ICD Codes	≥4 SLE ICD Codes	≥4 SLE ICD Codes & Ancillary Labs* Checked	≥4 SLE ICD Codes & ≥1 SLE Encounter from Rheumatology	≥4 SLE ICD Codes & ≥1 SLE Encounter from Rheumatology & Ancillary Labs Checked
n Patients	**9,826**	**5,648**	**4,118**	**3,226**	**2,743**
Antimalarial Use: n (%)	3,950 (40)	3,247 (57)	2,677 (65)	2,573 (80)	2,236 (82)
Aspirin Use: n (%)	1,592 (16)	1,158 (21)	907 (22)	767 (24)	682 (25)
SLE Nephritis: n (%)	1,575 (16)	1,338 (24)	1,151 (28)	964 (30)	894 (33)
Age First SLE ICD (SD)	47 (16)	45 (16)	44 (15)	43 (15)	42 (15)
Sex: n (%)					
F	8,713 (89)	5,100 (90)	3,699 (90)	2,907 (90)	2,468 (90)
M	1,110 (11)	547 (10)	419 (10)	319 (10)	275 (10)
Race: n (%)					
White	5,142 (52)	3,012 (53)	1,991 (48)	1,722 (53)	1,386 (51)
Black or African American	1,966 (20)	1,258 (22)	1,041 (25)	767 (24)	707 (26)
Asian	313 (3)	213 (4)	172 (4)	149 (5)	130 (5)
Other or Unknown	2,405 (24)	1,165 (21)	914 (22)	588 (18)	520 (19)

Legend: ICD = International Classification of Disease Codes; *ancillary labs checked = Complement 3 or 4 or anti-dsDNA antibody

Table 2. Clinical and Demographic Characteristics of Female Patients

	≥1 SLE ICD Codes	≥4 SLE ICD Codes	≥4 SLE ICD Codes & Ancillary Labs* Checked	≥4 SLE ICD Codes & ≥1 SLE Encounter from Rheumatology	≥4 SLE ICD Codes & ≥1 SLE Encounter from Rheumatology & Ancillary Labs Checked
n Patients	**8,713**	**5,100**	**3,699**	**2,907**	**2,468**
Antimalarial Use: n (%)	3,570 (41)	2,939 (58)	2,416 (65)	2,335 (80)	2,023 (82)
Aspirin Use: n(%)	1,363 (16)	1,010 (20)	786 (21)	673 (23)	597 (24)
SLE Nephritis: n (%)	1,340 (15)	1,158 (23)	994 (27)	834 (29)	770 (31)
Age First SLE ICD (SD)	47 (16)	45 (15)	43 (15)	43 (15)	42 (15)
Race n (%)					
White	4,552 (52)	2,714 (53)	1,782 (48)	1,541 (53)	1,239 (50)
Black or African American	1,789 (21)	1,159 (23)	957 (26)	705 (24)	658 (26)
Asian	285 (3)	202 (4)	164 (4)	144 (5)	127 (5)
Other or Unknown	2,087 (24)	1025 (20)	796 (22)	517 (18)	454 (18)

Legend: ICD = International Classification of Disease Codes; *ancillary labs checked = Complement 3 or 4 or anti-dsDNA antibody

Table 3. Detection of SLE Deliveries Across 5 SLE Phenotypes and 2 Delivery Phenotypes (Barnado et al.) in Female Patients

	≥1 SLE ICD Codes		≥4 SLE ICD Codes		≥4 SLE ICD Codes & Ancillary Labs* Checked		≥4 SLE ICD Codes & ≥1 SLE Encounter from Rheumatology		≥4 SLE ICD Codes & ≥1 SLE Encounter from Rheumatology & Ancillary Labs Checked	
n Patients	**n = 8,713**		**n = 5,100**		**n = 3,699**		**n = 2,907**		**n = 2,468**	
SLE Deliveries**	**≥1 Delivery Codes‡**	**≥4 Delivery Codes‡**	**≥1 Delivery Codes**	**≥4 Delivery Codes**	**≥1 Delivery Codes**	**≥4 Delivery Codes**	**≥1 Delivery Codes**	**≥4 Delivery Codes**	**≥1 Delivery Codes**	**≥4 Delivery Codes**
N Events	727	321	545	241	440	210	369	176	345	167
n Patients (%)	523 (5)	266 (3)	399 (7)	201 (4)	315 (8)	172 (4)	261 (8)	142 (4)	242 (9)	134 (5)
Age at Delivery (SD)	33 (5)	32	33	32	33	33	33	33	33	33
Min-Max	17-53	17-46	17-51	17-46	17-51	17-46	17-45	17-45	17-45	17-45
Race: N Events (%)										
White	412 (57)	170 (53)	298 (55)	121 (50)	223 (51)	99 (47)	194 (53)	85 (48)	176 (51)	79 (51)
Black or African American	146 (20)	65 (20)	121 (22)	53 (22)	107 (24)	50 (24)	83 (22)	39 (22)	80 (23)	37 (22)
Asian	48 (7)	23 (7)	43 (8)	22 (9)	33 (8)	19 (9)	28 (8)	16 (9)	26 (8)	15 (9)
Other or Unknown	121 (16)	63 (20)	83 (15)	45 (19)	77 (18)	42 (20)	64 (17)	36 (20)	63 (18)	36 (22)

Legend: ICD = International Classification of Disease Codes, Versions 9 and 10; *ancillary labs checked = Complement 3 or Complement 4 and anti-dsDNA antibody; ** = Delivery occurring after the first instance of a SLE ICD code: ‡ = Number of unique delivery-related codes less than 6 months apart required to identify one delivery encounter.

Table 4. Detection of Non-Delivery SLE Pregnancy Events*

	≥1 SLE ICD Codes	≥4 SLE ICD Codes	≥4 SLE ICD Codes & Ancillary Labs** Checked	≥4 SLE ICD Codes & ≥1 SLE Encounter from Rheumatology	≥4 SLE ICD Codes & ≥1 SLE Encounter from Rheumatology & Ancillary Labs Checked
n Patients	**n = 8,713**	**n = 5,100**	**n = 3,699**	**n = 2,907**	**n = 2,468**
Pregnancy Termination					
n Patients (%)	26 (0.3)	19 (0.4)	17 (0.5)	15 (0.5)	15 (0.6)
N Events***	26	19	17	15	15
Spontaneous Abortion					
n Patients (%)	51 (0.6)	38 (0.8)	30 (0.8)	24 (0.8)	24 (1)
N Events	59	45	34	28	28
Ectopic					
n Patients (%)	7 (0.1)	5 (0.1)	5 (0.1)	5 (0.2)	5 (0.2)
N Events	7	5	5	5	5

Legend: * = All events in table are those that occurred on or after the date of first SLE encounter; **ancillary labs checked = Complement 3 or 4 or anti-dsDNA antibody; *** = Separate events counted as those occurring more than 6 months apart; ICD = International Classification of Disease Codes, Versions 9 and 10.

Validation of the SLE algorithm used to identify women with SLE and for identification of ACR Guidelines for SLE Pregnancy Care

Training

Two medical students and one rheumatology fellow were trained to identify ACR and SLICC classification criteria attributes in the medical record. The first 10 cases were evaluated by the two medical students and met with the PI to review concordant and discordant results. Consensus was reached on the discordant results. A trained rheumatology fellow later joined the medical students to review the randomly selected medical records for validation. Midway through the validation exercise, the evaluators were tested on another sample of 18 cases to ensure consistency of results.

Validation quality control across three evaluators

We assessed the % positive responses for each ACR and SLICC classification criteria attribute across the 3 reviewers and agreement was excellent for 10/11 ACR attributes (hematologic disorder discordant) and 15/17 SLICC attributes (acute cutaneous and low complement discordant) in the initial check. The group met and reviewed the definitions of the attributes in question and a rerun of the quality control exercise demonstrated improved concordance accounting for multiple comparisons.

Based on the results of our initial data review, we selected ≥4 SLE ICD Codes, Ancillary Labs Checked (Complement c3, Complement c4, and anti-dsDNA antibodies). To validate our selection more fully, we assessed the algorithm over **[3,699 individuals identified by the ≥4 SLE ICD Codes & Ancillary Labs* Checked algorithm]** and selected a random sample of 365 patients (10% of the sample) for full adjudication and assessed concordance between the adjudication results and the algorithm. The number we report the percentage of patients that truly had SLE after manual review as noted by a provider's primary department that billed for the SLE ICD code (columns 1-3) in Tables 1-4 compared to those correctly identified by the algorithm phenotype. We included the other Barnado phenotype (columns 4 and 5) after we realized some patients did not have any data during manual review. As shown below in Table 5, 69-81% of the 365 patients were determined to have SLE through adjudication across the 5 algorithms tested.

Table 5. Performance of SLE Algorithms (Adjudicated 356 patients)

EHR Phenotype	Percent of Patients Correctly Identified with SLE
≥1 SLE ICD Codes	69
≥4 SLE ICD Codes	69
≥4 SLE ICD Codes & Ancillary Labs Checked*	69
≥4 SLE ICD Codes & ≥1 SLE from Rheumatology	81
≥4 SLE ICD Codes & ≥1 SLE from Rheumatology & Ancillary Labs Checked	81

Legend: ICD = International Classification of Disease Codes, Versions 9 and 10; * = Complement 3 or 4 or anti-dsDNA antibody ever conducted

Based on these results, we adjusted the algorithm to require that at least one of the 4 lupus diagnoses be from a rheumatologist. Our final identification algorithm is ≥4 diagnoses (with 1 or more diagnoses from a rheumatologist) and Ancillary Labs Checked (c3, c4, and anti-DNA). This will be the algorithm we use to identify our cohort of women with lupus for the remainder of the study, both at NU and within the CAPriCORN query.

Table 6. Summary of Patient Cohort to Validate ACR Guidelines for SLE Pregnancy Care

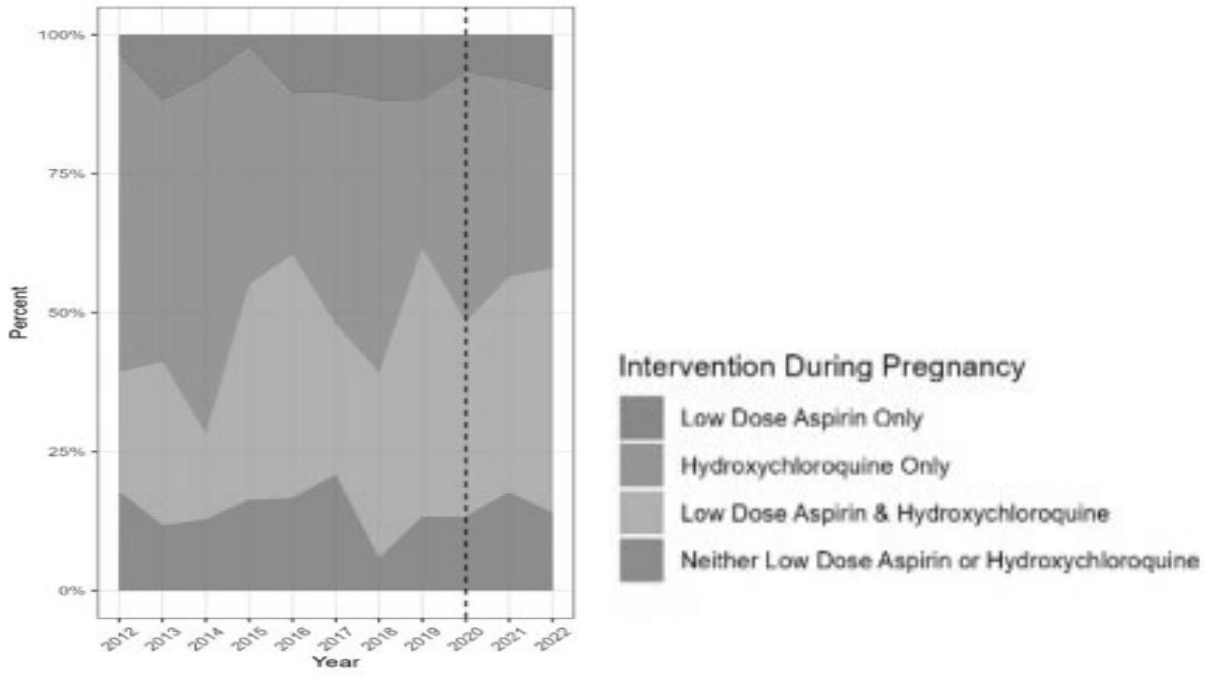
N Patients	**505**
ICD Coded SLE Encounters	
Mean (SD)	44.8 (46.9)
Median (Min, Max)	28.0 (4, 282)
Rheumatology SLE Encounters	
Mean (SD)	20.7 (23.6)
Median (Min, Max)	12 (1, 141)
Race N (%)	
White	243 (48)
Black or African American	140 (27)
Asian	30 (5)
Other or Unknown	92 (18)
Age at First SLE Encounter	
Mean (SD)	31.1 (7.22)
Median (Min, Max)	30.9 (15.8, 58.1)
Age at First SLE Pregnancy	
Mean (SD)	31.7 (5.8)
Median (Min, Max)	31.8 (18, 45)

Table 7. Comparison of Low Dose Aspirin (LDA) and Hydroxychloroquine (HCQ) Use Pre- and Post-ACR Recommendation Release in 2020

	Pre-2020	**2020-2022**
All Pregnancies		p=0.30
N Pregnancies (%)	**357**	**172**
0 Guidelines	51 (14)	26 (15)
LDA or HCQ	185 (52)	79 (46)
LDA & HCQ	121 (34)	67 (39)
0 Positive APL* tests		p=0.64
N Pregnancies (%)	**282**	**141**
O Guidelines	39 (14)	24 (17)
LDA or HCQ	145 (51)	64 (45)
LDA & HCQ	98 (35)	53 (38)
1 Positive APL test		p=0.81
N Pregnancies (%)	**48**	**11**
0 Guidelines	9 (19)	2 (18)
LDA or HCQ	26 (54)	5 (45)
LDA & HCQ	13 (27)	4 (36)
2 Positive APL tests		p=0.55
N Pregnancies (%)	**25**	**20**
0 Guidelines	3 (11)	0 (0)
LDA or HCQ	14 (52)	10 (50)
LDA & HCQ	10 (37)	10 (50)

*Anti-phospholipid tests

Figure 1. Implementation of ACR Recommendations Over Time



In this validation dataset, we detected modest increases in implementing ACR guidelines in our healthcare system. The limitation of a single site will be addressed using these algorithms in the multisite EHR, CAPriCORN to inform implementation studies. Future work will focus on improving uptake of guidelines and to foster dissemination of ACR guideline recommendations.

4. IMPACT

Since SLE is a rare disease, it is challenging for a single site to address solutions for the range of issues needed to improve pregnancy outcomes, including incorporating ACR aligned guidelines for reproductive health. Preliminary work by our team includes using EHR-based tools to identify and validate SLE, reproductive outcomes, and explore risk factors for disease severity focusing on lupus and lupus nephritis outcomes. The ELIPTCL team will apply these tools in the Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN) which spans a broad and diverse range of clinical settings in the Chicago metropolitan area including county and academic medical centers and federally qualified health centers. We will identify disease outcomes and explore the risk factors for disease severity and adverse outcomes by mapping outcomes of interest and risk factors to data elements in the PCORnet CDM currently used by the network to harmonize queries. The analysis plan for aim 1 uses logistic regression models to examine the effect of disease severity and morbidity on poor pregnancy outcomes, using generalized estimating equations to account for correlation between pregnancies in the same patient. The analysis plan for aim 2 uses logistic regression models to assess the effect of ACR guidelines-guided care on poor pregnancy outcomes, using generalized estimating equations to account for correlation between pregnancies in the same patient.

Short-term Impact of ELIPTCL

1. Expand upon existing EHR-based tools to assess SLE and pregnancy outcomes including ACR-aligned guidelines for reproductive health
2. Validate revised EHR-based tools to describe SLE and pregnancy outcomes including ACR-aligned guidelines for reproductive health
3. Describe SLE and pregnancy outcomes using revised EHR-based tools including ACR-aligned guidelines for reproductive health
4. Assess risk factors to identify clinical, medication, healthcare utilization, and environmental influences as measured by Area Deprivation Index (ADI) scores to inform modifiable risk factors to improve pregnancy outcomes

Long-term Impact of ELIPTCL

1. Share EHR-based tools to assess SLE and pregnancy outcomes throughout PCORnet and other clinical research groups
2. Develop EHR-based tools and embed ACR-aligned guidelines for reproductive health within those tools as decision aids
3. Assess pregnancy outcomes using EHR-based tools, e.g., adherence versus non-adherence to ACR-aligned guidelines for reproductive health or other modifiable risk factors identified in the current proposal
4. Expand use of EHR-based tools to assess pregnancy outcomes for other chronic rheumatic diseases where similar needs have been identified by patients and their caregivers

5. CHANGES/PROBLEMS

COVID-19 pandemic led to delays in initial approval of the Northwestern IRB protocol focused on developing algorithms for data extraction, preliminary data extraction for validation, and performing the validation in the NMEDW per IRB/HRPO approved protocols. The project is approximately 12 months delayed due to these unanticipated obstacles. This delay also impacted the development of the central IRB protocol for CAPriCORN as well as adapting the queries to the common data model used by the network. CAPriCORN has a central IRB, CHAIRb, that all participating members have agreed to use as the governing IRB for network queries. While the protocol was initially approved on 8/31/2023, changes to the query implemented during the query validation process within the network required changes to the protocol and re-approval by CHAIRb before the protocol could be reviewed by HRPO. Both CHAIRb and HRPO have now approved the full protocol and we anticipate that the query will be implemented across the network by 1/31/2024 and final data analysis will occur after the dataset is received. We anticipate all work will be complete by 8/2024

6. PRODUCTS

Nothing to report.

7. PARTICIPATING AND COLLABORATING ORGANIZATIONS

The collaborating organizations provided guidance on the algorithms to be tested primarily in year 2. Due to administrative delays in preparing and then invoicing for year 2 activities, remaining invoices were paid in year 3. The remaining tasks for the collaborating organizations are to review abstracts and manuscripts for presentation at professional meetings and for publication respectively in year 4. Therefore, the progress reports from the collaborating organization will be submitted at the end of year 4.

8. SPECIAL REPORTING REQUIREMENTS

Nothing to report

9. APPENDICES

Nothing to report

Name	Rosalind Ramsey-Goldman
Project Role	Principal Investigator
Research Identifier	0000-0001-8712-787X
Nearest Person Month Worked	1 CM
Contribution to Project	Principal Investigator (PI) as the contact PI, responsible for oversight of study reports, IRB submissions, and also scientific perspective provides clinical input for algorithm development

Name	Dorothy Dunlap
Project Role	Health Services Researcher
Research Identifier	N/A
Nearest Person Month Worked	2 CM
Contribution to Project	Assists with statistical methodology.

Name	Holly Robin Milaeger
Project Role	Research Program Manager
Research Identifier	N/A
Nearest Person Month Worked	2 CM
Contribution to Project	Oversees IRB submissions and regulatory requirements.

Name	Theresa L Walunas
Project Role	Biostatistician
Research Identifier	0000-0002-7653-3650
Nearest Person Month Worked	2 CM
Contribution to Project	Works on bioinformatics and algorithms for the project.

*Name of Individual: Rosalind Ramsey-Goldman
Commons ID: ramseygoldman

Other Support

ACTIVE

*Title: Lupus Clinical Investigators Network (LuCIN)

Major Goals: The goal of this program is to create a group of lupus investigators to conduct rich and meaningful lupus investigations. LuCIN Overarching Goals are to conduct safe, reliable and coordinated evaluation of new lupus treatments, facilitate patient access to novel clinical studies, maintain centralized expertise in lupus clinical research, optimize lupus outcome measures by improving existing methodologies,utilize archived clinical data and biospecimens to better understand lupus and promote the advancement of quality lupus research by facilitating the training and mentoring of new clinical research investigators

*Status of Support: Active
Project Number: Agmt 1/7/2020 Amnd 5
Name of PD/PI: Ramsey-Goldman
*Source of Support: Alliance for Lupus Research
*Primary Place of Performance: Northwestern University
Project/Proposal Start and End Date: (MM/YYYY) (if available): 06/2016 – 12/2023
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
6. 2023	0.12 calendar months

*Title: Lupus Intervention Fatigue Trial (LIFT)

Major Goals: We designed the Lupus Intervention Fatigue Trial (LIFT) to formally test the effectiveness of a motivational interviewing program intervention versus a patient educational program control to reduce fatigue in persons with lupus
*Status of Support: Active
Project Number: R01AR071091
Name of PD/PI: Ramsey-Goldman
*Source of Support: NIH/NIAMS
*Primary Place of Performance: Northwestern University
Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/2018 – 07/2024
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
5. 2023	1.8 calendar months
6. 2024	1.8 calendar months

*Title: EHR-based LongItudinal Cohort to Explore Pregnancy OuTComes in SLE (ELIPTCL)

Major Goals: The overarching objectives of this proposal are to use Electronic Health Record (EHR)-basedtools to describe occurrence and predictors of heterogeneous pregnancy outcomes in maternal SLE across multiple sites, and to assess the impact of ACR guideline-

guided care in maternal lupus using real-world datacollected at the point of care as the foundation for study evaluation.

*Status of Support: Active
Project Number: W81XWH
Name of PD/PI: Ramsey-Goldman
*Source of Support: Department of the Army
*Primary Place of Performance: Northwestern University
Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2020 – 08/2023 (2nd NCE pending)
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
4. 2024	0.12 calendar months

*Title: Developing and Disseminating Programs to Build Sustainable Lupus Awareness, Knowledge, Skills and Partnerships

Major Goals: The goal is to provide guidance and technical assistance to the American College of Rheumatology to plan, implement and evaluate all deliverables of the CDC project and serve as rheumatology expert on scientific review panel for medical school outreach and lupus education outreach project.

*Status of Support: Active
Project Number: NU58DP006908-01-00
Name of PD/PI: Ramsey-Goldman, Rosalind
*Source of Support: CDC via subcontract from American College of Rheumatology
*Primary Place of Performance: Northwestern University
Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2020 – 9/2023 (continuance requested)
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2024	0.60 calendar months

Title: Northwestern University (NU) Core Center for Clinical Research (CCCR)

Major Goals: While we will provide broad support, we will particularly seek to drive this theme: prevention strategy and intervention development through lifestyle, behavioral, medical, and rehabilitative solutions, built on a foundation of person-centered assessment in daily life and community engagement. Because our CCCR is centered on the goal to improve how persons feel and function in their daily lives, focuses on community and personal experience, and builds upon the wearable and portable technology revolution, we are positioned to have substantial impact on work within and beyond our institution.
*Status of Support: Active
Project Number: P30AR072579
Name of PD/PI: Sharma, Leena
*Source of Support: National Institute of Arthritis and Musculoskeletal and Skin Diseases

*Primary Place of Performance: Northwestern University, Chicago
Project/Proposal Start and End Date: (MM/YYYY): 09/2017-8/2027
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
7. 2024	1.2 calendar
8. 2025	1.2 calendar
9. 2026	1.2 calendar
10. 2027	1.2calendar

*Title: Leveraging Community-Academic Partnerships and Social Networks to Disseminate Vaccine-Related Information and Increase Vaccine Uptake Among Black Individuals with Rheumatic Diseases
Major Goals: Our community-academic partnership will design, implement and evaluate an intervention that trains community leaders with rheumatic conditions to disseminate vaccine-related information through their social networks in Black communities to promote racial justice in vaccine uptake.
*Status of Support: Active
Project Number: R01AR080089
Name of PD/PI: Ramsey-Goldman/Feldman
*Source of Support: NIH
*Primary Place of Performance: Northwestern University
Project/Proposal Start and End Date: (MM/YYYY) (if available 05/2022 – 04/2027
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
3. 2024	2.40 calendar months
4. 2025	2.40 calendar months
5. 2026	2.40 calendar months

*Title: The Relationship Between Brain Macrophages and Cognitive Dysfunction in Systemic Lupus Erythematosus

Major Goals: Since diagnostic strategies for NP-SLE are limited, patients with NP-SLE often fail to achieve remission using current therapies and side effects from treatment are substantial, the ultimate objective is to utilize these research discoveries to help in the development of targeted laboratory diagnostic tests as well as safer, more effective therapies for NP-SLE.
*Status of Support: Active
Project Number: R01AI170938
Name of PD/PI: Cuda, C.
*Source of Support: NIH
*Primary Place of Performance: Northwestern University
Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/2022 – 06/2027
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
3. 2024	0.12 calendar months

Year (YYYY)	Person Months (##.##)
4. 2025	0.12 calendar months
5. 2026	0.12 calendar months

*Title: A Phase II Sequential Dose-escalation Study Evaluating the Safety and Feasibility of Allogenic Umbilical Cord Derviced Mesenchumal Stromal Cells for the Treatment of Adults w/Treatment Refractory Lupus

Major Goals: Northwestern University will be a clinical site for a planned clinical trial and will enroll 13 participants in the trial by interacting with the trial PI and co-investigators and complete all CRFs, comply with data management and analysis plans for the trial and also complete site-specific tasks such as the local IRB and research unit applications, budget and clean cell facility utilization.

Status of Support: Active
Project Number: MUSC18-053-8D365
Name of PD/PI: Gilkeson, G.; Role: Site Investigator
Source of Support: Lupus Foundation of America, Inc.
Primary Place of Performance: Medical University of South Carolina
Project/Proposal Start and End Date: (MM/YYYY) (if available): 10/2017-03/2024
* Total Award Amount (including Indirect Costs): Northwestern University site only
* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
5. 2024	2.19 calendar months

*Title: Differentiating clinical characteristics between two subtypes of antiphosphatadylethanolamine

Major Goals: The data from this investigation will enable us to better understand the clinical characteristics of aPE, including relationships between the two subtypes and with APS. This information will help determine whether the two subtypes of aPE are intrinsically different entities; and the findings will guide basic mechanistic research and inform future clinical studies that would impact practice.

*Status of Support: Active
Project Number: R21AI171491
Name of PD/PI: Zhao/Ramsey-Goldman
*Source of Support: NIH
*Primary Place of Performance: Northwestern University
Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/2022 – 06/2024
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2023	0.48 calendar months

PENDING

None

IN-KIND

*Summary of In-Kind Contribution: None

***Overlap:** None

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature: DocuSigned by: Rosalind Ramsey-Goldman 6256442911E54E7...

Date: 06-Dec-2023

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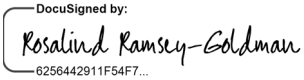
Rosalind Ramsey-Goldman rgramsey@northwestern.edu Security Level: Email, Account Authentication (None)	DocuSigned by:  6256442911F54F7... Signature Adoption: Pre-selected Style Using IP Address: 165.124.110.94	Sent: 12/6/2023 2:23:55 PM Viewed: 12/6/2023 2:25:10 PM Signed: 12/6/2023 2:26:17 PM

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Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

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Completed	Security Checked	12/6/2023 2:26:17 PM

Payment Events	Status	Timestamps

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