PROTOCOL TITLE:

Utilizing a Lupus Patient Navigator Program (LPNP) to Address Barriers to Care Related to Access to Preventive and Specialty Healthcare, Medication Adherence and Health Literacy in Systemic Lupus Erythematosus (SLE) for Minority Patients

PRINCIPAL INVESTIGATOR:

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1.0 Objectives / Specific Aims

To improve health care delivery to minority patients with SLE at highest risk for poor outcomes, utilizing patient navigators to address barriers to care related to access to preventive and specialty healthcare, medication adherence, and health literacy.

2.0 Background

Despite recent progress in the diagnosis and treatment of SLE, minorities continue to bear the greater burden of disease with disproportionately higher morbidity and mortality compared to white patients with SLE (1). Longitudinal studies of patients with SLE demonstrate a strong genetic component impacting the development of SLE and the risk of severe disease (2); however the development of irreversible SLE-related and medication-related organ damage is undeniably complicated by patient socioeconomic factors (2, 3). Patients frequently are sent home from clinic or the hospital with powerful immune suppressants and an incomplete understanding of risks and benefits. In the lupus Medicaid population, a large fraction of patients have medication non-adherence leading to increased risk of hospitalization (4). Every year 25% of SLE patients are hospitalized and 16% of those are readmitted within 30 days (5). Other factors associated with poor outcomes include transportation (6) and family caregiving obligations among others. Patients return with either complications of inappropriate treatment or organ failure (nephritis, pulmonary hemorrhage) from their disease.

Although we cannot change the patient's genetic risk factors or socioeconomic status, we can identify and modify the barriers to SLE care that lead to poor health outcomes (such as difficulty accessing primary and specialty healthcare, low health literacy, harmful attitudes and beliefs regarding SLE and its treatment).

3.0 Intervention to be studied

Patient navigator programs have been utilized successfully to improve health outcomes by reducing barriers to care for patients with several chronic diseases, including cancer, diabetes, HIV/AIDS, cardiovascular disease, and chronic kidney disease. A recent systematic review of patient navigator interventions found that 45 of the 67 randomized controlled trials reported statistically significant improvements in the primary outcomes (7). Since the first patient navigation program in the 1980s focused on breast cancer outcomes, there has been over a decade of successful use of patient

navigators in oncology. Consequently, for accreditation, cancer centers are required by the American College of Surgeons Commission on Cancer to provide patient navigation services as of 2015 (https://www.facs.org/quality-programs/cancer).

The navigator services most commonly provided include facilitation/coordination of care, practical support, including transportation and financial assistance, appointment scheduling and reminders, education and psychosocial support (7). The most effective patient navigators address both health system barriers and patient barriers (examples shown in Table 1).

Targeted interventions have been proposed to address the common barriers to care among patients with SLE (8-10), but a comprehensive patient navigator approach utilizing novel interventions based on evidence from prior studies, such as the one proposed, has yet to be described in the literature.

Table 1 - Features of the proposed Lupus Patient Navigator Program.

Barriers to Optimal Care	Lupus Patient Navigator Program Features	Examples of Patient Navigator (PN) Interventions
Missed / Forgotten / Cancelled Appointments	Facilitate care (referrals, communication, coordination) / Appointment scheduling / Appointment reminder calls	Patient unable to navigate scheduling system to make specialist appointments; PN facilitates by contacting specialty offices and coordinating appointments based on patient's location needs.
Lack of Reliable Transportation	Practical support with transportation options	Pt is unfamiliar with transportation option in their area; PN provided public transportation schedules, instruction on how to schedule Medicaid van.
Lack of Information / Misinformation	Health literacy promotion, delivery of culturally tailored health information addressing patient and caregiver attitudes and beliefs	PN discovers patient and caregiver misperceptions about Lupus; PN provides publicly available resources from the Lupus Foundation of America website.

Poor Adherence to Treatment	Encouragement of treatment adherence through the use of medication diary / Assistance with enrolling into medication assistance programs	Patient unable to obtain medications due to lack of insurance; Assist patient with completing pharmaceutical patient assistance applications.
Financial Concerns	Practical support in finding community financial resources and public insurance options	Patient reports difficulty with utility bills; PN helps contact appropriate agencies for assistance.

4.0 Study Endpoints

Improvement in Medication Adherence, Improvement in patient-reported lupus-specific disease status (measured by the LupusPRO), Improvement in Adherence with Primary Care / Specialty Care Visits, Lab and other Study Appointments.

Racial Discrimination will be measured using the validated 9-item Experiences of Discrimination (EOD) measure, which includes an index of racial discrimination experiences ever experienced. The EOD is a widely used and validated measure of racial discrimination. This short, self-report instrument is based on a prior instrument used in the Coronary Artery Risk Development in Young Adults (CARDIA) study validated in AA and Latino participants and has been previously used for measuring experiences of racial discrimination in AA women with SLE. (11).

5.0 Inclusion and Exclusion Criteria / Study Population

Criteria for Inclusion:

INTERVENTIONAL GROUP (n=25): 1) Self-identified Minority. 2) Patients ≥ 18 years of age as documented in the electronic medical record. 3) Meeting either American College of Rheumatology or SLICC Classification Criteria for SLE as documented in the electronic medical record (12, 13). 4) Ability to speak and understand English by self-report. 5) In the past six months having ≥ 1 missed clinic or diagnostic study/laboratory visit as documented in the electronic medical record, self-reported failure to adhere with prescribed medical therapy for SLE, or the participant is newly diagnosed with SLE. 6) In the past six months having been prescribed at least one immunosuppressive medication for SLE activity as documented in the electronic medical record regardless of whether taking the medication. 7) Have telephone access.

USUAL CARE GROUP (n=25): Meet criteria 1, 2, 3, 5, 6, 7 above for interventional group. All data from healthcare utilization and medication compliance will be collected via the CCCR biorepository request process. See data collection guidelines for this group below (Sections 12 & 13).

Criteria for Exclusion (Interventional Group only): 1) Unwilling or unable to give informed consent. 2) Being a prisoner or institutionalized individual. 3) Without telephone access. 4) Do not meet all of the inclusion criteria listed above.

Criteria for Exclusion (Usual Care Group only) 1) Do not meet usual care inclusion criteria above.

Recruitment will be enhanced by MUSC having specialized lupus clinics already in place dedicated to the care of patients with SLE.

6.0 Number of Subjects

Sample size of n=25 patients in the Patient Navigation Group and n=25 patients in the Usual Care Group.

Patients who meet eligibility criteria and provide informed consent to participate in the LPNP will be enrolled up to the sample size goal of 25 patients. Upon completion of all study visits for the Patient Navigation Group, 25 additional patients who meet the inclusion criteria will be identified through the CCCR biorepository study to be included in the Usual Care group. Healthcare utilization and medication compliance data will be provided via a formal request (see Sections 12 & 13 below) to the CCCR and provided to study staff.

7.0 Setting

MUSC Rheumatology clinics, MUSC inpatient setting

8.0 Recruitment Methods

The patient's primary rheumatologist can refer the patient to the PI/study staff for eligibility review after discussing with the patient. If needed, Epic (EMR) rheumatology-specific clinic schedules and charts of those patients seeing those rheumatologists (PI/Co-I) will be reviewed weekly for patients with lupus and self-identified as a minority. These patients will be contacted by PI/Study Staff only if they not opted out for research contact. Additionally, outreach and advertising materials will be used to promote and introduce the study to potential candidates. Material will be made available to PI/Co-I's for discussions with pts, within MUSC Rheumatology Clinic waiting rooms for pt initiated access/interest, as well as hardcopy and electronic versions (email) to potential pts as appropriate following preferred communication method of the pt as noted in Epic. Outside of any direct in-person exchange/presentation, there will be an accompanying notification that explains the contact (i.e. brochure). Eligibility will be confirmed by the PI. Subjects will be contacted via telephone and/or at their clinic visit.

We do not anticipate difficulty enrolling 25 patients into the LPNP intervention group within the initial eight months of the 24-month funding period, given the large number of high-risk patients followed at MUSC. For example, based on recent experience and EMR administrative data review, at least 35% of the 1320 patients with SLE followed at MUSC in the last two years meet the demographic (age, race, disease duration) and medication criteria.

9.0 Consent Process

IRB approved personnel are authorized and qualified to obtain consent. The informed consent document may be sent to potential subjects prior to scheduling a screening visit, either by mail or email, for their review.

Informed consent will be obtained in a private clinic room. The consent will be explained to the subjects and they may take time to read the document; subjects will be given ample time to review the ICF and ask questions; subject's questions will be answered by the investigator and/or study staff. After signing, subjects will be given a signed/dated copy of the ICF. There is no wait period. No study procedures will be performed prior to obtaining written informed consent.

To reduce barriers to enroll in the study during times of unexpected campus and/or clinic shutdowns (pandemics, weather occurrences, etc.), remote consent option will be available. Participants will have the option to complete consent 1) via MUSC's doxy.me system (tele consent) or 2) via REDCap electronic consent (e-consent) combined with a phone discussion. These procedures for consenting remote study participants are in line with the IRB approved procedures and are supported through MUSC SCTR Services. All doxy.me signed consent forms will be saved as PDF files within our study records. Signatures on the consent form may be obtained electronically via REDCap/doxy.me. To minimize concerns of errors/compliance with execution, Doxy.me will be the primary mode of eConsent with REDCap serving as a backup method in case there are system compatibility or end user concerns experienced. Participants will be encouraged to print and/or save a copy for their resource. If they do not have the ability to do so, a copy of the executed ICF will be provided to them at their next in-person visit or mailed per their preference.

No undue coercion or influence will be utilized for recruitment. The amount of compensation subjects may receive is nominal. All possible subjects will be treated the same. All patients that may screen fail or choose not to participate in the study will not have their standard of care altered or lose access to care.

10.0 Study Design / Methods

Schedule of Events	Screening Call	In-Person Baseline Visit [α]	Monthly Call (Months 1,2,4,5,7,8,10,11) After Baseline*	Appointment Reminders (15 Days & 2 Days Before 3, 6, 9 Month Visit)**	Post 3, 6, 9 Month Visit[α]	Appointment Reminders (15 Days & 2 Days Before Post 12 Month Visit)	Post 12 Month Visit[α]
Participation Assessment	X						
Informed Consent & HIPAA		X					
Steps To Care Intake Assessment Form		**X**					
Steps To Care Reassessment Form			X		X		X
Participant Completed Assessments: Healthcare Resource Use Survey, Test of Functional Health Literacy		**X**					
MacArthur Ladder, Experiences of Discrimination (EOD) measure		X					**X**
LupusPRO		X			**X**		**X**
Medication Adherence Diary Review		X			X		X
Participant Completed Assessments: Perceived Stress Survey, Social Support Survey & Modified Picker Survey, Patient-Centered Care Questionnaire		X					X
Appointment Reminder Calls				X		X	
Patient Satisfaction with Interpersonal Relationship with Navigator (PSN-I) survey							X
As Needed							
1 Week F/U Call After Medication Change	Medication changes can occur at any time during the study. Medications to be included are those prescribed for your SLE.						

*Monthly Call window = +/- 7 calendar days.

**Appointment Reminder window = +/- 2 business days.
α All in person visits can be done in clinic or remotely via doxy.me

Screening:
PN will assess patient willingness to participate in the study as well as eligibility via a phone call, remote visit, in person at their clinic appointment, or once stable during an inpatient hospital stay.

Baseline In Person or Remote Visit:
Upon enrollment (Baseline visit) and signing of informed consent and HIPAA authorization, the PN will provide the following questionnaires, surveys and diaries:
1) Steps to Care Intake Assessment Form,
2) Healthcare Resource Use Survey,
3) LupusPRO survey,
4) Test of Functional Health Literacy,
5) Medication Adherence Diary,
6) Perceived Stress Survey,
7) Social Support Survey & Modified Picker Survey Patient-Centered Care Questionnaire,
8) Experiences of Discrimination (EOD) measure,
9) MacArthur Scale of Subjective Social Status (MacArthur Ladder).

Post 3, 6, & 9 Month In Person or Remote Visits:
1) Medication Adherence Diary review,
2) Steps to Care Reassessment Form,
3) LupusPRO survey.

Post 12-Month In Person or Remote Visit:
1) Medication adherence diary review,
2) Steps to Care Reassessment Form,
3) LupusPRO Survey,
4) Perceived Stress Survey,
5) Social Support Survey,
6) Modified Picker Survey Patient-Centered Care Questionnaire,
7) Experiences of Discrimination (EOD) measure,
8) MacArthur Scale of Subjective Social Status (MacArthur Ladder).

Monthly Phone Calls post signing of informed consent:
1) Steps to Care Reassessment Form

The PN will contact enrolled patients to provide appointment reminders. Contacts can be via phone, text, email, or MyChart as preferred by participant. These appointments are not only standard of care rheumatology visits but also associated to the research study in question. These contacts will be completed 15 days and 2 days prior to rheumatology clinic visit.

Additionally, the PN will calls the patients one week following any changes in medications for their SLE (per primary Rheumatologist or patient reported) and will ensure patient has filled in proper

information on their Medication Adherence Diary during that contact. The PN will respond to phone calls from participating patients for health and general questions, notifying the appropriate medical provider when necessary and documenting all patient-initiated calls in the EMR. The PN will assess whether the patients' basic needs are being met (i.e. are there adequate resources for food, housing, medications, etc.) and make referrals for support services as needed (to include referrals for dietary modification, smoking cessation, exercise, obesity prevention, psychiatry, and substance abuse).

For each of these in-person visits with surveys, participants will be compensated $10 (for a total of $50.00 over 12 months of participation). Compensation will be delivered via ClinCard. The in-person PN visits will be planned in conjunction with scheduled outpatient clinic visits.

For the Usual Care Group only: As stated above, in order to properly obtain data, while minimizing risk to patients in this study, the study staff will only utilize data for those patients that have already enrolled in the Division of Rheumatology Core Center for Clinical Research (CCCR; Pro21985). These patients will have provided properly executed HIPAA authorization to utilize Protected Health Information through the CCCR for optional research portions of the CCCR study (see General Comments of IRB application to review CCCR HIPAA Authorization). Data on healthcare utilization and adherence to prescribed medications based on pharmacy records would be collected on the Usual Care group as part of standard quality of care monitoring, which are allowed to be collected through the CCCR; Pro21985. This data will be provided through a formal request process, reviewed by the executive committee of the CCCR, and provided to this study's staff via this request. Note that this group of patients (Usual Care) will not have a formal informed consent process completed and executed as only analysis of data already collected for standard of care is necessary and falls under the HIPAA Authorization for the CCCR.

11.0 Specimen Collection and Banking

No specimens will be collected.

12.0 Data Management

The MUSC CCCR Patient Resource Core (Pro00021985) will act as an honest broker for the provision of clinical data of patients that fit criteria and are already enrolled in the CCCR study. The clinical data provided to the PN and PI of this study will include all data listed in sections 4.0 & 10.0 and will be provided to study staff de-identified. The data provided will only include 25 patient data sets for the "Usual Care" group that has not had contact with the patient navigator and serves as the control group for this study.

Analyses will be primarily descriptive in nature. Means, standard deviations, medians, inter-quartile ranges, and proportions will be reported on each outcome of interest, as appropriate. These statistics will be reported at baseline, 3 months, 6 months, and at 12 months for the primary outcome measure (Medication Adherence) and all secondary outcome measures. The secondary outcome measures are 1) Adherence with Primary Care and Specialty Care Visits, 2) Adherence with Lab and other Study Appointments, 3) Healthcare Utilization, 4) Disease-related Damage, 5) Corticosteroid Use and 6) Patient-Reported Outcomes.

In addition to results reported by our site, we will report results from our collaborating site, University of Alabama at Birmingham (UAB), during their implementation of the LPNP protocol.

Analyses will include estimates of site to site variability utilizing a combined MUSC and UAB dataset. All data sharing will be de-identified and maintained on MUSC's supported REDCap platform. Shared data and analyses were included in the Scope of Work executed by NIH subaward funding of 3P30AR072582-03S1, Improving Minority Health in Rheumatic Diseases.

Although this is not a randomized trial, we will use statistical methods such as propensity score weighting (36) to gain an understanding of how the use of PNs improves outcomes (e.g. medication adherence) when compared to usual care. Generalized linear mixed models will be used in conjunction with propensity score weighting to compare treatment group outcomes and estimate relevant effect sizes while adjusting for relevant baseline covariates (e.g. age, SLEDAI) and accounting for repeated measures within patients over time.

Since we will have all healthcare utilization data over the 12-month time, calculations will also be performed to indicate how intervention and control patients compared monthly throughout the study. These data will help us design a larger randomized, multi-center, clinical trial. The pilot study will be extremely valuable both in demonstrating feasibility and in providing data for sample size estimation for our next step trial.

Since this is a pilot study, our sample size of n=25 patients in the PN group and n=25 patients in the "Usual Care" group were selected primarily to ensure that we can assess feasibility of providing this intervention in this high-risk population. Having n=25 patients in each group will also allow us to estimate group-specific outcomes with relatively strong precision (i.e. within ± 0.3 standard deviations for continuous outcomes and ±10%-20% percentage points for proportions). All this information will be vital for designing a future, definitive randomized controlled trial. In obtaining preliminary estimates of effectiveness, our sample sizes will also provide sufficient power (>80%) to detect moderate differences in medication adherence rates between treatment groups, assuming 2-sided hypothesis testing and an alpha level of 0.05.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

The investigator and other study personnel will keep confidential any information related to this study, all data and records generated during conducting the study, and will not use the information, data, or records for any purpose other than conducting the study. These restrictions do not apply to: (1) information that becomes publicly available through no fault of the investigator or site personnel; (2) information that is necessary to disclose in confidence to an IRB solely for the evaluation of the study; (3) information that is necessary to disclose in order to provide appropriate medical care to a patient; or (4) study results that may be published in an aggregate fashion.

All data will be stored on MUSC Network Storage with survey results entered into a secure MUSC REDCap database, only accessible by personnel approved on this study application with MUSC login credentials. The data from the two institutions (MUSC and UAB) will be maintained separately, with data entry and editing performed only by IRB-approved personnel specific to each site.

Patients will be assigned an identification number. Personal identifiers will not be accessible to individuals beyond the investigative site. Confidentiality will be maintained by the use of codes for identifiers. All study related documents (physical paper documents, if needed) and materials will be

kept in secured locked file cabinets in a locked office space of the Division of Rheumatology with limited access by non-study personnel.

14.0 Withdrawal of Subjects

Subjects can withdrawal at any time during the 12-month study simply by verbally telling the PN either in person or over the phone they wish to withdraw.

15.0 Risks to Subjects

Confidentiality: There is the potential risk of loss of confidentiality. Every effort will be made to keep information confidential; however, this cannot be guaranteed. After the study is completed, the data may be placed in a central storage location or public database. This will include all the information learned from this study and not just information specific to an individual patient. Any data will not include patients' names or other information that can identify an individual patient. The purpose is to make study data available to other researchers who must request permission to use it.

Questionnaires/Surveys: The questions that will be asked may be sensitive in nature and make the patient feel uncomfortable. The patient may be asked personal questions that the patient finds distressing. The patient may refuse to answer any question(s) that they do not wish to answer.

16.0 Potential Benefits to Subjects or Others

If having a Patient Navigator improves a patient's compliance with medication adherence, clinic and lab appointments, the patient's overall health and quality of life may improve. It may also reduce the SLE related damage to vital organs which may improve overall health and quality of life. However, this cannot be guaranteed.

17.0 Sharing of Results with Subjects

Since all study subjects are patients of the MUSC Rheumatology clinics, their primary Rheumatologist will have access to data in the patient's EMR. Results of survey data will not be shared with the participants. All other data is a part of the participant's standard of care and thus is continuously shared with them via their care providers.

18.0 Drugs or Devices (if applicable)

No drugs or devices will be used in this study.

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