Addressing Disparities in Lupus Care Through an Integrated Care Management Program (Rheum-ICMP)

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Background and Significance

Systemic lupus erythematosus (SLE) is a chronic multi-system autoimmune disease with significant morbidity and mortality that disproportionately affects women of child-bearing age and non-white racial/ethnic groups.[1,2] The prevalence of SLE is more than twice as high in African American individuals compared to White individuals and is the sixth leading cause of death for African American and Hispanic women aged 25-34 years old.[1-3] Using data from nationwide Medicaid, the public insurance for low income individuals, our team has shown that African American SLE patients suffer from significantly higher rates of acute care utilization (emergency department (ED) visits, hospitalizations), as well as end-stage renal disease (ESRD), serious infections, cardiovascular disease, and mortality than White SLE patients.[2,4-7] We have also demonstrated that Medicaid beneficiaries consistently fail to meet established metrics for high-quality ambulatory SLE care resulting in a disproportionate burden of avoidable adverse outcomes.[8-10] In addition, in this vulnerable population, more than 75% of SLE patients are nonadherent to their medications and this is associated with increased avoidable acute care use.[5,11-13] Within our Boston community, we conducted focus groups with predominately African American SLE patients from federally designated medically underserved areas (Dorchester, Mattapan and Roxbury), and uncovered significant need for improved access to coordinated care among patients receiving care at academic medical centers.[14] At the BWH Arthritis Center, among 107 patients surveyed, only 23% completely adhered to their medications, 86% described at least one barrier to consistent medication use or rheumatology care, and depressive symptoms were common.[15,16] We recently found that among 110 SLE patients receiving care at BWH, >50% experienced discrimination of some kind that they ascribed to their race, gender or age. In addition, between July 2015-March 2017, despite the need for close monitoring of disease activity and medication use, only 60% of BWH SLE patients kept their rheumatology appointments as scheduled.

To begin to reduce the racial/ethnic and socioeconomic status disparities in SLE care and outcomes, there is an urgent need to identify patients at the BWH Arthritis Center at increased risk for avoidable acute care use and adverse outcomes and to address barriers to high-quality, consistent ambulatory care for SLE. No similar program has been tailored to the needs of vulnerable rheumatology patients. Our goal is to adapt the existing, sustainable Partners

Healthcare integrated care management program (iCMP) infrastructure to meet the needs of vulnerable SLE patients and ultimately, to scale this intervention to reduce disparities among all high-risk patients with rheumatic diseases. The iCMP program utilizes nurses, social workers and community health workers to coordinate care for high-risk, high-cost primary care patients. This program has reduced acute care use and has been successfully adapted to support complex chronic disease management for complex diseases including heart failure and end-stage renal disease.

Our team has demonstrated significant racial, ethnic, and socioeconomic disparities in receipt of high-quality SLE care, in medication adherence, and in adverse outcomes nationally, in Boston, and at our BWH Arthritis Center. To reduce disparities, high-risk patients must be identified, barriers unique to each patient must be understood, and sustainable, coordinated, high-quality care must be delivered. We piloted a 6-month intervention using patient navigators without prior medical training to understand and address barriers to medication adherence among >100 rheumatology patients at our center. In response to the needs encountered, navigators performed a range of tasks including facilitation of patient-MD communication, medication/diagnosis education, and development of individualized strategies to improve adherence.[15] This prior intervention highlighted the clear need for additional chronic disease care support and coordination, however it was funded as part of a research study and was not part of the clinic's long-term infrastructure and therefore the benefits could not be sustained. In addition, due to their lack of medical training, the navigators could not participate in complex chronic disease management. Partners iCMP is a well-established, sustainable, scalable primary care-based program for high-need, high-cost patients that provides care coordination, builds trusting relationships, and addresses mental and physical health issues and social determinants.[17, 18] Using a trained nurse at the center of care coordination, disease-specific iCMP models for congestive heart failure and ESRD have similarly proved to be feasible and effective. SLE patients are unique in that most are young, and many are healthy prior to and soon after diagnosis, meaning that they may be missed by standard Partners high-risk patient identification algorithms at the time when their disease course is most modifiable. In addition, they are disproportionately from vulnerable populations and many SLE-related adverse outcomes are avoidable if high-quality ambulatory care is received.[19] Outside of our institution, a Chicago-based study showed that patients who received integrated lupus care rather than general rheumatology care had

significantly better lupus quality metric performance.[20] A care model utilizing a nurse care coordinator and social worker at the University of Rochester has led to a decrease in no-show rates, hospitalizations, and 30-day readmissions for high-risk patients.[21] BWH serves as the largest provider of lupus care in New England, and it is essential that we keep pace with other leading centers to establish the infrastructure needed to identify and care for our most vulnerable patients.

The innovation of Rheum-iCMP originates from:

- The ability to leverage the established effective infrastructure and expertise of the existing iCMP program, while additionally arming iCMP nurses with SLE-specific training with a focus on disparities
- The identification of high-risk SLE patients accounting for unique characteristics that differentiate them from other chronic disease patients
- The formal analysis of the ability of Rheum-iCMP to improve the receipt of high-quality ambulatory care and minimize avoidable acute care use
- The sustainability of Rheum-iCMP beyond a year-long grant and the scalability to expand to vulnerable patients with other rheumatic diseases
- The direct response to needs raised by our BWH patients and our greater Boston SLE community members to better coordinate their complex medical care

Specific Aims

Aim 1: To systematically identify and track SLE patients receiving care at BWH with SLE-related avoidable conditions leading to substantial acute care utilization, as well as SLE patients with inconsistent ambulatory care use, placing them at significant risk for future avoidable acute care use and poor outcomes.

Aim 2: To understand the social determinants that contribute to acute care use and avoidable outcomes among SLE patients using semi-structured interviews and a photovoice method.

Aim 3: To deliver the "Rheum-iCMP" program to these high-risk SLE patients through a pilot program, to determine whether coordinated, comprehensive care and specific nurse training in

rheumatology improves high-quality, consistent ambulatory care use and ultimately reduces avoidable acute care use.

Subject Selection

We plan to identify English and Spanish-speaking high-risk SLE patients (age ≥18, with diagnosis of SLE, receiving primary care at BWH) who are in the Partners' risk contract (Medicaid, Medicare and certain commercial insurances) with BWH primary care physicians (PCPs) from three sources. First, we will use the BWH Lupus Registry (IRB 2001P000300, PI: Costenbader), which is updated regularly and includes SLE patients actively receiving care at BWH. Second, we will identify SLE patients using via Partners EHR using our validated SLE algorithm (IRB 2016P001428, PI: Feldman) and look specifically at those receiving primary care within the BWH system. We will link both BWH Lupus Registry patients and patients meeting our algorithm to claims data through the Population Health Repository (IRB 2013P001479, PI: Vogeli, IRB 2017P000339, PI: Feldman, and IRB 2018P003040, PI: Feldman). We will then identify patients with increased healthcare utilization, including emergency department visits and/or hospitalizations during the preceding 3 years, and who are at risk for avoidable outcomes (rheumatology appointment no-shows/same-day cancellations within the same period). We will also apply the Partners' Center for Population Health high-risk algorithm to both cohorts to identify additional high-risk patients. We will then reach out to the identified patients' primary care providers or their rheumatologist for their approval to send them a letter on their behalf inviting them to participate or asking them to introduce the study to their patients with a fact sheet. Third, we will ask rheumatologists to refer SLE patients who might benefit from Rheum-iCMP since a similar referral system has been successful within BWH-wide iCMP. Our requirement for inclusion is that the patient has lupus and a BWH PCP. We will focus on patients with PCPs in the Jen and Fish Centers and may expand to the Faulkner and other BWH-affiliated primary care practices where BWH iCMP is active as well depending on recruitment numbers and iCMP nurse availability. If patients prefer correspondence to occur, once enrolled, via email, we will do this via Patient Gateway or send secure email. For patients already enrolled in iCMP, we will use the above strategies (lupus registry, algorithm application, rheumatologist-referral) to identify patients. In addition, we will apply a SLE-related ICD-9/10 code filter to the list of all

patients enrolled in the iCMP program at BWH and then conduct chart reviews and use data from RPDR in order to determine additional already enrolled patients who have SLE.

Subject Enrollment

Our total enrollment goal is 140. We plan to newly enroll 40 SLE patients prospectively using a stepped wedge design. Among these 40 patients, 20 patients to start Rheum-iCMP right away, and 20 patients to receive monthly educational materials by mail for 4 months and then start Rheum-iCMP. We will invite these patients to participate in a semi-structured interview that includes asking participants ahead of time to take photographs (with a disposable camera we will provide) of their neighborhoods and their homes, in order to begin a conversation about the social determinants that contribute to their care-seeking behaviors. We are requesting a waiver of documentation of informed consent. A fact sheet will be given to all potential participants and will be reviewed by a trained member of the study team who is not the patient's direct physician and verbal consent will be obtained. We are requesting a waiver because this program is a modification of an existing program (iCMP) that is part of standard of care procedures at the BWH. With the stepped wedge design of this program, everyone who agrees to participate will receive the intervention (participation in rheum-iCMP). This program does not pose more than minimal risk and based on the Partners-wide experiences with iCMP, it has been proven to improve patient care and reduce avoidable acute care use. The goal of this rheumatology-specific iCMP program is to study an enhanced iCMP for lupus patients to ultimately scale it rheumatology-wide. By requiring written consent, we feel that we may unnecessarily exclude patients from receiving a program that would be beneficial for their health that is already standard of care at BWH. We plan to assess iCMP nurse and MD satisfaction with Rheum-iCMP using surveys at the end of 12-16 months, and we will supply information sheets with the surveys and infer nurse and physician consent by completion of the survey.

Partners-wide, 190 SLE patients are actively enrolled in the iCMP program. We expect that 100 of these SLE patients are already enrolled in BWH iCMP. We plan to examine EHR and claims data for these patients pre and post additional rheum-specific iCMP nurse education. However, we do not plan to ask for survey completion, since this iCMP program is considered standard of care, and because we do not feel that this will involve more than minimal risk, we do

not plan to consent these individuals to allow us to examine their medical records. We will invite these patients to participate in the semi-structured interview.

Study Procedures

Selected iCMP nurses will receive a 4-hour training using unique educational materials already developed by our team (IRB 2017P001824, PI: Feldman) that specifically address SLE-related racial, ethnic and socioeconomic disparities.[22,23] We will compare SLE-related quality metrics, adherence to rheumatology appointments, and acute care use 12 months prior to rheum-iCMP vs. during rheum-iCMP and then for the subsequent 12-24 months. We will provide SLE-specific training to the iCMP nurses of the SLE patients who are already enrolled in BWH iCMP at BWH and compare measures extractable from medical records pre-iCMP, during iCMP but pre-SLE-specific iCMP nurse training, and during Rheum-iCMP (post-nurse training) for N=100. As described above in subject enrollment, we anticipate 100 patients already enrolled in iCMP with SLE (who we will not newly enroll or collect surveys from) and for these patients, we will conduct chart reviews for the 12-months prior to iCMP enrollment, during their enrollment and, if available for the subsequent 12-24 months after discharge from the standard-of-care program. In addition to directly reviewing charts, we will also use RPDR and the Enterprise Data Warehouse (EDW) for data such as appointment no shows not available through RPDR for analyses in the pre-, during, and post- iCMP study periods.

We plan to continue to collect data on appointment and medication adherence, SLE quality metrics and acute care utilization to measure impact. During the intervention period, our project coordinator will set up a sustainable EPIC system for tracking appointment no-shows and SLE quality metrics (e.g. lab monitoring, contraceptive use). We will collect the following surveys at baseline and 12 months after the start of rheum-iCMP: a lupus checklist of quality metrics, medication adherence and medication beliefs using the MASRI survey and the Beliefs about Medications scale, SLE disease activity using SLAQ, mental health using the MHI-5, social determinants of health using a survey already integrated into the Partners EHR system, the PROMIS global health scale short form, and racial discrimination using the Everyday Discrimination Scale. We will also collect baseline demographics information via a demographics survey. A physician member of the team will complete a lupus checklist for each

of the enrolled patients in EPIC and route the checklist to the iCMP nurse, rheumatologist and PCP as part of the standard of care baseline iCMP needs assessment. To complement the surveys, we will also conduct chart reviews with a focus on social determinant of health factors collected as part of standard of care by the iCMP nurses. We will conduct the chart reviews for the following time periods: 12 months prior to the rheum-iCMP study period, during the rheum-iCMP study period, and 12-24 months following the end of the study period. For individuals who unenrolled before the end of the 12-month study period, we will stop the chart review at the date of unenrollment. We may decide to share the results of the previously mentioned surveys with the patient's physician or iCMP nurse if doing so could improve the patient's care. For individuals who have already completed one round of surveys and received the old information brochure, we will call them and document the date and time of the conversation asking permission to convey information from surveys that might help their care to their physicians and/or iCMP nurse. We will also determine acute care utilization (e.g. ED visits, hospitalizations) using partners risk contract claims data (IRB 2013P001479, PI: Vogeli, IRB 2017P000339, PI: Feldman, and IRB 2018P003040, PI: Feldman). We will also use surveys at the end of 12-16 months to assess patient, iCMP nurse, MD satisfaction. Patients will have the choice of either completing the surveys on REDCap or in paper form at outpatient appointments or via mail. If the patient prefers to complete a survey using REDCap, we will email an individual link to the subject using Send Secure. For longer term quality metrics 12-24 months past the intervention period, we will work with the Center for Population Health's team to set up a tracking system that has Partners-wide claims data linked with electronic medical records. For the 100 patients already enrolled in the iCMP intervention, we will collect data on process measures (e.g. appointment no- shows, subspecialty and primary care visits, acute care utilization, receipt of standard-of-care SLE monitoring laboratory tests, vaccinations, preventive care screenings and medications) and social determinants of health. We also plan to use natural language processing methods to extract social determinants of health data from unstructured fields (e.g. notes) in electronic medical records. We will compare the ability of these methods to extract the social determinants of health data with the gold standard chart reviews (e.g. sensitivity, specificity). We will also collect these data for the 40 patients.

Photovoice Semi-Structured Interviews

We will invite the 40 newly enrolled patients as well as patients already actively enrolled in the iCMP program to participate in an optional semi-structured interview that we plan to record and transcribe regarding social determinants of health. Patients who decline to participate in this can still take part in rheum-iCMP. Participants will be given a disposable camera, or have the option to use their smartphone, and asked to take 10-15 photographs of their home and neighborhood. Once the photographs are received, a trained qualitative research moderator and the applicant will conduct ~60-90 minute semi-structured, in-depth photo-elicitation interviews. Photographs will be discussed first to empower and engage the participant and to provide context for the interview. Participants will be asked to 1) select the photographs for discussion, 2) contextualize each image and tell a story, 3) describe what is really happening and how it relates to their life and 4) propose suggestions for what can be done to improve any barriers described. Inherent to the Photovoice method is an "action" component. Participants will be explicitly asked how these photographs capture issues related to their health and healthcare use and what specific interventions could improve access to consistent care. The moderator will integrate questions that address social determinants (see Moderator guide) as they relate to potentially avoidable acute care use. For example, the interviewer will ask about neighborhood safety in the context of waiting for public transportation to keep appointments. If this is a barrier, the interviewer will ask for suggestions to improve this, such as expanded access to subsidized door-to-door transit for disabled individuals.

Biostatistical Analysis

We plan to continue to collect data on appointment adherence, SLE quality metrics and acute care utilization to measure impact. During the intervention period, our project coordinator will set up a sustainable EPIC system for tracking appointment no-shows and SLE quality metrics[25] (e.g. lab monitoring, contraceptive use). We will assess medication adherence using the MASRI survey[24], a lupus checklist with quality metrics, SLE disease activity using SLAQ[26] and acute care utilization (e.g. ED visits, hospitalizations) using partners risk contract claims data. We will also use surveys to assess patient, iCMP nurse, MD satisfaction, as well as patient-reported outcome measures (e.g. quality of life) [28]. Surveys will be collected at outpatient appointments or by mail. For longer term quality metrics past the intervention period, we will work with the Center for Population Health's team to set up a tracking system that has Partners-wide claims data linked with electronic medical records. For the 100 patients already enrolled in

the iCMP intervention for whom we are doing data collection only (no direct patient interaction/intervention), we will collect data on process measures (e.g. appointment no-shows, subspecialty and primary care visits, acute care utilization, receipt of standard-of-care SLE monitoring laboratory tests, vaccinations, preventive care screenings and medications). We will also collect these data for the 40 patients. This is a pilot study. One of our primary measures is to reduce ambulatory and subspecialty care no-show rates for the highest risk patients. We estimate that the no-show rate is about 70% and we aim to reduce this to 20%. We would need a total of 30 patients (15 in each arm) to have 80% power to detect this difference and there have been multiple unexpected withdrawals due to insurance and PCP related issues out of our study's control, which is why we chose N=40 for our intervention. We will used paired t-tests and Wilcoxon rank tests depending on distribution to compare combined arm data post vs. pre study period for the primary outcomes.

Photovoice Semi-Structured Interviews

We will use visual analysis strategies to directly interpret the photographs. This includes close examination of every part of each image, an understanding of the timing and location of each photograph in the series, whether they include people/family members, whether images are posed or candid, and an assessment of the patterns and themes that emerge across the photographs. The elicitation interviews will be audio-recorded, transcribed verbatim, and entered into Dedoose for analysis. Dedoose is an affordable, cross-platform application designed to store, organize and code qualitative and mixed methods data, and can include both text and photographs. We will analyze interview data using a modified grounded theory approach to identify major themes relating to the targeted aim of understanding the social determinants that contribute to avoidable care use, and practical considerations for interventions. This modified approach allows us to accomplish this rather than purely identifying an overarching theory for the impact of social determinants on health. We will apply grounded theory principles including open, axial and selective coding, as well as memo writing, to identify concepts and categories, which we then will group into themes. We will organize our data in a set of tables to facilitate the constant comparison of themes across participants based on age, sex, race/ethnicity and education to increase the internal validity of results.

Risk and Discomforts

There is a very small risk to participants of breach of confidentiality, for which we have several protections in place. All patient information will be stored with unique identifiers and not names. This information will be stored on a secure password-protected computer (database inside the PHS firewall) in a locked office. Only approved study staff will have access to the data. The PI and her collaborators/Co-Is will be available to all participants to provide support and answer questions that arise.

Potential Benefits

It is expected that study participants will experience a decrease in avoidable acute care use and improved access to sustained high-quality coordinated SLE care. Participants enrolled in rheum-iCMP remain in the program after the survey assessments are completed, since we are using existing infrastructure. Ultimately, we hope that this will lead to a societal benefit of improved access to coordinated SLE-care, social work, mental health and pharmacy services for vulnerable SLE patients and reduced disparities among high-risk SLE patients. Participants will also receive a $20 gift certificate for the return of any surveys and $30 additional for participation in the interview. Interview participants will have their parking paid for during the interview.

Monitoring and Quality Assurance

Data quality assurance protocols will be developed to ensure that a set of operational techniques and activities are in place. The database manager will examine data files for data entry errors and plausibility of extreme outliers using a series of statistical methods and will resolve any specific data discrepancies or inconsistencies. Accuracy and completion of data sources will be reviewed on a regular basis.

Unanticipated problems involving risks to subjects or other problems including adverse events will be reported to the PHRC in accordance with the PHRC unanticipated problems including adverse events reporting guidelines.

If any participant experiences what they perceive as an adverse event related to the information provided, the PI will report this to the IRB immediately.

Per our correspondence with RISO, we will do the following to protect the security of our data:

- Partners REDCap will be used
- Should any emails be sent to participants, the blind copy function (BCC) must be used when sending to more than one patient/research subject, in order to protect the confidentiality of recipients
- Inform participants to set up a PIN code/encrypt their smartphones as part of formal study procedures or Informed Consent
- Participants will be provided with a disposable camera and send back to study team to develop the photos
- Participants will take photos of their environment, and will be instructed not to focus on taking pictures that could contain anything that may be individually identifying (i.e. themselves, other people, license plates, etc.)
    - Photos will be reviewed with participants at their study visit
    - Photos will be scanned and saved on a Partners SFA that is only accessible by authorized study staff
    - Original hard copy photos will be disposed in a secure shredding bin following the interviews
    - Should photos contain any identifying information, they will be redacted by covering over with a black box before storing on Partners SFA
        - Access to SFA should be reviewed (and revoked) as study staff changes
- Participants may also use their smartphone cameras to take pictures and send back to the study team via "send secure"
    - Inform participants to delete pictures pertaining to research study from their phones upon sending and obtaining confirmation that photos have been received
- Participants will be provided with a 'tip' sheet that will provide instructions for picture taking and expectations of the interview sessions for acknowledgement
- Audio recordings and subject code key will be saved on Partners SFA
- Dedoose will be used for qualitative data analysis and data visualization
    - Dedoose will never have access to PHI
    - Only deidentified transcripts from interviews will be uploaded for coding and analysis
    - Data is encrypted in transit
- For the Deedoose web portal:
    - HTTPs is enforced over HTTP
    - TLS version in use is 1.2 or superior
    - Weak ciphers are disabled
    - Modern ciphers are configured as preferred
    - Server ciphers preferred over client's
    - Certificates are valid and issued by a publicly-trusted certificate authority
    - The web portal will be accessed only from devices compliant to Partners workstation policies
    - Access should be reviewed (and revoked) when study staff changes
- Access to web portal by study staff requires a username and password:
    - Passwords must be a minimum of 8 characters
    - Passwords must be alphanumeric, containing at least one of each.
    - Cannot reuse 4 previous passwords.

    - Passwords must be changed immediately if either the password or the system is or may be compromised
    - Passwords must not be displayed in clear text when they are being input into an application.
    - Passwords must be changed every 90 days
    - Users must be uniquely identified; no shared or group accounts without security authorization
    - Passwords may not be shared
    - User access must be terminated immediately upon termination or change of responsibilities
    - Passwords should not be the same used as regular Partners credentials for workstations
- Only Partners Workstations / Laptops in use for the research
    - Password requirements from above
    - Encryption at rest is in place
    - Up-to-date malware protection including antivirus, spyware detection and removal tools
    - Personal firewall is enabled
    - Manufacturer supported operating system with current updates, if available for the device
    - Crowdstrike End Point protection installed

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