IMPLEMENTING THE DECISION-AID FOR LUPUS (IDEAL STRATEGY)

Protocol Number: 300002272
National Clinical Trial (NCT) Identified Number: NCT03735238
Principal Investigator: Jasvinder A. Singh, MD, MPH
IND/IDE Sponsor: University of Alabama at Birmingham
Funded by: Patient-Centered Outcomes Research Institute
Version Number: 15
6/10/2020

Table of Contents

1 STATEMENT OF COMPLIANCE

The Implementation of Decision Aid for Lupus Patients in Practice Settings for Shared Decision-Making (SDM): IDEAL Study will be conducted in accordance with the International Conference on Harmonization Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and Patient Centered Research Outcomes Institute (PCORI) Terms and Conditions of Award. The Principal Investigator (Jasvinder Singh, MD, MPH) will ensure that no deviation from, or changes to the protocol will take place without prior agreement from the PCORI, and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials have been submitted and approved by the University of Alabama at Birmingham (UAB) Institutional Review Board (IRB). Any amendment to the currently approved protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; in be obtained from any participants who provided consent, using a previously approved consent form.

2 PROTOCOL SUMMARY

2.1 Synopsis

Title:	**I**mplementation of **De**cision-**A**id for **L**upus Patients in Practice Settings for Shared Decision-Making (SDM): **IDEAL** study.
Study Description:	We are proposing to put into practice a shared decision-making (SDM) strategy (a decision making process jointly shared by patients and their health care providers) using an individualized, computerized decision aid (DA; a tool to help each person make individual treatment decisions) for Systemic lupus erythematosus (SLE), also commonly called lupus, which is culturally appropriate for lupus patients.
Objectives:	**Specific Aim 1**: Conduct a formative evaluation in 16 diverse clinics to assess stakeholder needs and identify clinic and contextual characteristics (e.g., readiness for change, physician attitudes, patient barriers) to inform strategy component selection and influence implementation effectiveness of lupus DA (Aim 2). **Specific Aim 2:** Assess the effectiveness of a multi-component (standardized and tailored) strategy for the implementation of the DA in 16 lupus clinics (minimum 35 patients/clinic) by examining changes in subjective and objective measures of implementation effectiveness over 27-months. **Specific Aim 3:** Identify opportunities for sustaining and disseminating the DA via semi-structured debriefing interviews with key clinic informants of Aims 1 and 2 and patients and develop a manual that provides step-by-step implementation guide for incorporating the DA into regular lupus clinic visits and care pathways.
Study Population:	Male/Female Lupus Patients Key Clinic Personnel
Description of	Participants will be recruited from n=16 sites, listed below:

Sites/Facilities Enrolling Participants:	1. Baptist Health, 2. Ohio State University 3. Loyola University, 4. Vanderbilt University, 5. University of California Los Angeles, 6. Medical University South Carolina, 7. Baylor University, 8. Emory University, 9. Northwestern University, 10. Northwell Health, 11. University of Mississippi, 12. University of California San Diego, 13. University of Alabama, Birmingham (UAB) 14. Cedars-Sinai Hospital, 15. University of Chicago, 16. University of Illinois at Chicago
Study Duration:	27 months
Participant Duration:	6 Months

2.2 Table 1. Schedule of Activities (SOA)

IDEAL Study Timeline and Milestones

Activity (by Quarter(Q) of Study)	Q 1	Q 2	Q 3	Q 4	Q 5	Q 6	Q 7	Q 8	Q 9	Q 10	Q 11	Q 12
Study Management and Recruitment												
Finalize study consent, recruiting materials, and train staff	X											
Submit for IRB Approval at UAB + 15 sites	X											
Network Meta-Analysis for Decision-Aid and updating content	X											
Participant enrollment												
Aim 1: Semi-Structured Interviews & surveys; Clinic Staff	X	X										
Aim 2: Patient Enrollment												
Begin study enrollment		X										
Enrollment 25% complete				X								
Enrollment 50% complete						X						
Complete study enrollment										X		
Clinic Personnel Exit Interview**												
Aim 2: Clinic Personnel surveys		X		X				X				
Aim 3: Semi-Structured Interviews; Patients + Clinic Staff										X		
Study Coordinator 6 month Survey		X		X		X		X		X		X
Draft abstracts/manuscripts for presentation publication											X	
Submit abstract/manuscripts for presentation/publication												X
Data Management and Analysis												
Finalize study questionnaires and analysis plan	X											
Begin data analysis										X		
Complete Data Analysis and Implementation manual												X
Complete data analysis of study endpoints												X
Reports to Funding Agency (PCORI)												
D&I evaluation Plan Template completed	X											
Complete Interim Progress Report		X				X			X			
Complete update on evaluation work				X								
Evaluation of sustainability and next steps												X
Final Progress Report												X

**Only conducted if clinic personnel transitions to another position or leaves the organization.

Aim 1 clinic personnel semi-structured Interviews & surveys *focused on understanding organization's ability to change, the clinic structure and function, clinic flow and the clinic's team interaction* will be done once at the baseline.

Aim 2 clinic personnel surveys will be done at 0, 6, 12, and 24 months *to assess the acceptability, appropriateness, feasibility, success, permanence of the DA*. Baseline surveys will be completed in the Q1-Q2. *Health care utilization by patients (inpatient and urgent care) and DA penetration will be assessed using administrative data*.

Aim 2 patient assessments with surveys will be done on the day of clinic visit (0-month in-person), and then at 3- and 6-months, to be done via phone, mail, or at the regularly scheduled clinic visit per the patient participant preference. Surveys will assess patient satisfaction with DA, its acceptability and feasibility, patient perception of DA usefulness (PDM), decision conflict, decision involvement, care process/communication (IPC, audiotaped conversation), DA review time.

Aim 3 clinic personnel semi-structured Interviews will be done once with same people as in aim 1 to assess the level of DA integration into clinics and the implementation lessons learnt.

Aim 3 patient semi-structured Interviews will be done once with 2 patients/clinic.

3 INTRODUCTION

3.1 Study Rationale

In a PCORI funded and recently completed multicenter randomized trial, 301 high-risk adult women with lupus kidney disease, including racial/ethnic minorities with low socio-economic status, either received the lupus DA (decision-aid) or the American College of Rheumatology (ACR) lupus paper pamphlet with information on treatments. Compared to the ACR paper pamphlet, people who used the lupus DA had a much greater decrease in decisional conflict (uncertainty in choosing options) for immunosuppressive drugs and were much more likely to choose the treatment option most consistent with their values, having viewed information that mattered the most for the treatment decision. Compared to the pamphlet group, more patients rated the information in lupus DA to be excellent for understanding the impact of lupus (49% vs. 33%), risk factors (43% vs. 27%), medication options (50% vs. 33%), evidence about medications (47% vs. 24%); and rated the ease of use of materials higher (51% vs. 38%). This study will put into practice a shared decision-making (SDM) strategy, using the individualized, culturally sensitive, computerized decision-aid for systematic lupus erythematosus (SLE) patients.

3.2 Background

Lupus is a rare disease with significant health impact, disparities and decision-making challenges - Lupus is a rare autoimmune disease of young women with significant health outcome disparities (PCORI priorities), with 2.4-times higher mortality than age-matched controls. It affects 0.1% of the population, but lupus nephritis (kidney disease) accounts for 2% of all end-stage renal disease in the U.S. Decision-quality in lupus is poor; many patients decline lifesaving immunosuppressive medications, due in part to the lack of recognition of benefits and a fear of harms. Long-term immunosuppressive drug and glucocorticoid (called “steroid”, “Medrol” or “prednisone”) therapy, often lifesaving and kidney-saving, can be complex and has significant risks including serious infections, shingles and infertility, significantly affecting young women of child bearing potential.

3.3 Risk/Benefit Assessment

3.3.1 Known Potential Risks

Beyond potential anxiety from responding to questions and considering treatment options, there are no anticipated risks to participating in Specific Aim 2 (patient review of decision-aid, feasibility and acceptability assessments) and Specific Aim 3 (semi-structured quantitative interviews with selected patients). Although it is possible that clarification of treatment options will increase the indecision in some patients, previous studies of decision-aids show that more information leads to a decrease in decisional conflict. Similarly, the clinic staff providing their opinions as part of Aims 1-3 could have potential anxiety from responding to questions.

3.3.2 Known Potential Benefits

Participants will not directly benefit from participation in this study; however, it is our hope that patients will be better informed about their treatment options.
The major benefit of this research is for lupus patients in the future. If we can implement this decision-aid tool in regular clinics and integrate it with the patient clinic flow, patients with lupus will have access to it in the future. The lupus decision-aid tool may help with patient decision making and informed choice and patients may be more satisfied with their decision-making. This non-proprietary tool in the public domain will be available to all lupus patients for use in decision-making regarding immunosuppressive drugs.

3.3.3 Assessment of Potential Risks and Benefits

A potential benefit from this study is that the knowledge gained will provide patients valuable information about lupus and its treatment, as well as to inform clinicians about the best way to implement the decision-aid into normal clinic workflow.

We will take the following precautions to avoid/minimize risks to participants:

Patient participant initial data and responses to questionnaires will be captured during regularly scheduled lupus clinic visits. Follow-up surveys will be conducted via phone, email, or in the clinic visit depending on the preference of the patient. All clinic personnel surveys and interviews will be conducted during general work hours (even before or after their shift). All semi-structured in-depth interviews will be captured via phone and transcribed for accuracy as soon as possible. All data (except data from semi-structured interviews) will be entered into coded electronic case report forms (CRF) and will be checked by study personnel daily for accuracy. On a quarterly basis study investigators and research team will review GCP, human subject's protections/confidentiality, and study procedures. The research team will meet biweekly to review recruitment, enrollment, source documents, and electronic case report forms; in the event an adverse event occurs this will be reported to the UAB IRB at the time of continuing review. All serious adverse events (SAEs) will be reported to the IRB and PCORI within 48 hours of the Principal Investigator becoming aware of the event. All research team members will be informed by the PIs about any unanticipated problems involving risks to the participant. If any protocol changes are needed, the PIs will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval unless necessary to eliminate apparent immediate hazards to the research participant. In such cases, the IRB will be promptly informed of the change following implementation (within 1 week).

Considering the aim of this study is to determine best practices for implementation of a treatment decision aid it poses no more than minimal risk to participants. We will use a secured database to minimize the risk of disclosure of personal health identifiers (PHI) therefore no Data Safety Monitoring Board (DSMB) will be convened.

4 OBJECTIVES AND ENDPOINTS

Specific Aim 1: Conduct a formative evaluation and introduction to the DA in 16 diverse clinics to assess stakeholder needs and identify clinic and contextual characteristics (e.g., readiness for change, physician attitudes, patient barriers) to inform strategy component selection and influence implementation effectiveness of lupus DA (**Aim 2**). Penetration will be assessed by evaluating the proportion of eligible patients reviewing the DA overall and in each site. Patient healthcare utilization outcomes (e.g., inpatient visits and ER/urgent care visits) will be assessed similarly.
Specific Aim 2: Assess the effectiveness of a multi-component (standardized and tailored) strategy for the implementation of the DA in 16 lupus clinics (minimum 35 patients/clinic) by examining changes in subjective and objective measures of implementation effectiveness over 27 months. Objective measures will be assessed in both clinic personnel and in patients. Clinical personnel will evaluate perceived acceptability of intervention measure for the DA, perceived DA implementation success, and perceived DA permanence. All will be assessed on a Likert-type scale. Similarly, patients will evaluate perception of DA usefulness, patient satisfaction for the DA, perceived intervention appropriateness measure for the DA, and perceived feasibility of intervention measure for the DA. All of these patient assessments will be measured on a Likert-type scale.
Specific Aim 3: Identify opportunities for sustaining and disseminating the DA via semi-structured debriefing interviews with key clinic informants of Aims #1 and patients of Aim 2 and develop a manual that provides step-by-step implementation guide for incorporating the DA into regular lupus clinic visits and care pathways.

5 STUDY DESIGN

5.1 Overall Design

Design of trial: Observational, case study design
Single or multi-site: Multisite
Methods to minimize bias: The observational study design explicitly incorporates varied context and baseline capabilities between the clinics. This approach could lead to potential selection bias issues. To minimize the potential for this selection bias we have recruited clinics with varied characteristics both private and academic; general rheumatology and lupus clinics to implement the DA from a wide-range of geographical areas.

5.2 Scientific Rationale for Study Design

5.2.1 Rationale for an Observational Study Design

An observational study design was chosen to explicitly incorporate the varied contexts and baseline capabilities between practices.

5.3 End of Study Definition

A patient participant is considered to have completed the study if he or she has completed the baseline visit, and both three and six month telephone interviews. If he/she is selected to participate in the "debriefing", completion of the study is considered after the above has been completed and the "debriefing" has been completed.
A clinic personnel participant is considered to have completed the study if he or she has completed the formative evaluation (Aim 1); and the standard and targeted decision aid implementation strategies (Aim 2).
If he/she is selected to participate in the semi-structured interview (Aim 3), completion of the study is considered after the interview is completed.

5.4 Inclusion Criteria

Specific Aim 1 Clinic Personnel:

- Clinic personnel involved in the care processes of lupus patients are eligible to participate**.**

Specific Aim 2 Patients:

- Men and women ≥ 18 years of age
- All races/ethnicities
- Diagnosis of Systemic Lupus Erythematosus

Specific Aim 2 Clinic Personnel:

- Clinic personnel involved in the care processes of lupus patients are eligible to participate**.**

Specific Aim 3 Clinic Personnel:

- Participating clinical personnel from Specific Aim 1

Specific Aim 3 Patients:

- 2 patient participants randomly chosen from patient participants from Specific Aim 2 from each of the 16 clinic sites.

5.5 Exclusion Criteria

Specific Aim 1 (Clinic Personnel):

- Clinic personnel who are not involved in the care processes of lupus patients.

Specific Aim 2 (Patients):

- No diagnosis of lupus

- Not English or Spanish speaking
- Visually impaired
- Altered mental status

Specific Aim 2 (Clinic Personnel):

- Clinic personnel who are not involved in the care processes of lupus patients.

Specific Aim 3 (Clinic Personnel):

- Clinic personnel who are not involved in Specific Aim 1.

Specific Aim 3 (Patients):

- Patients with lupus who are not involved in Specific Aim 2.

5.6 Lifestyle Considerations

There are no lifestyle considerations applicable to this study.

5.7 Screen Failures

Screen failures are defined as participants (patients) who consent to participate in IDEAL but do not meet eligibility criteria or withdraw consent before reviewing the DA or answering the assessments. Screen failures are also defined as those who meet eligibility criteria but do not consent to participate in the study.

We will collect a minimal set of screen failure information to ensure transparent reporting of screen failure participants, to meet the Consolidated Standards of Reporting Trials (CONSORT) publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, and eligibility criteria.

5.8 Strategies for Recruitment and Retention

Key Clinic Personnel Recruitment

Prior to implementation of the DA, the clinic personnel will be exposed to a brief video animation about the DA content and a link to the DA. We will recruit and conduct semi-structured in-depth interviews via phone with 6-8 key clinic personnel that will address perceived barriers to implementing the decision-aid. The clinic personnel will be identified by the site PI and or/ clinic champion and asked to participate. The site PI and/or the clinic champion will select the clinic personnel to ensure that all areas in each clinic are represented (LPN/RN, Physician, physician-extenders (Physician assistants/nurse practitioners) and Front Desk Staff) (Specific Aim 1).

In addition, all clinic personnel (up to 15 per site), will participate in an online survey (Specific Aim 1) and a regular online survey to assess DA acceptability, feasibility, success etc. (Specific Aim 2). Each site will receive a list of all the clinic personnel emails from their clinics nurse/business manager. The study coordinator will send an email with a link to complete the Qualtrics survey. Reminder emails will be sent to non-responders 1- and 2-weeks after the initial email.

At the conclusion of the study, we will conduct semi-structured in depth interviews via phone with the same 6-8 key clinic personnel, as well as 2 patients selected by the PI to identify implementation lessons learned, and assess anticipated barriers to sustaining the decision-aid after the study is completed (Specific Aim 3).

Semi-structured interviews will be done by phone to reduce participant burden.

Key Clinic Personnel Retention

Clinic personnel will be retained by periodic check-ins (email and phone call) from the research team to ensure the standardized capacity-building activities are being maintained. The clinic champion will be the point of contact to keep staff motivated and consistent while implementing the decision-aid. A refresher training course will be administered to each site every six months and as needed during Aim 2. There will be a portal available (e.g., Google Docs) for all sites to share suggestions and best implementation practices. The standardized and tailored implementation activities (webinars, trainings, coaching, DA reminder in patient intake process, audit and feedback, team huddles/clinic meetings) will keep the clinic staff invested in the value of shared decision making (Specific Aim 2).

Patient Participant Recruitment

We will recruit and enroll up to 3,000 adults (≥ 18 years of age) from 16 geographically diverse sites who have been diagnosed with lupus. Recruitment will include men and women of all races/ethnicities.

Advertisements (flyers) may be placed in clinic rooms and in participating site publications. Flyers will contain information about the study, as well as the study coordinators contact information. Depending on each sites clinic structure other recruitment strategies will be implemented such as decision aid information offered on the patient portal, waiting room TV, or a paper-based version of the decision aid mailed to the patient before the visit detailing the study and time demand. Coordinators will review the inclusion and exclusion criteria prior to approaching potential patient participants during their regular clinic visits about being in the study.

Potential patient participants who agree to participate will be given a non-signature consent form detailing the study purpose and procedures. Participants will also be required to sign a HIPPA document, since some personal health identifiers (PHI) may be obtained (medical record number, conversations between patient and physician). Each patient participant will be informed of the study compensation of $50 at the baseline visit and $10 for each follow-up visit that is completed. Once the study has been explained, the non-signature consent form read over by the participant, and the HIPPA document is signed, study procedures will begin.

The study investigators and research team will have meetings weekly to monitor site recruitment and to determine any intervention for poor recruitment. In the event a problem is identified by either study site PI or staff, a teleconference/webinar will be scheduled to review the issue. These teleconferences/webinars will include discussions of overall recruitment status and identified barriers to recruitment experienced by the site with the study team.

Patient Retention

Three and six month follow-up surveys will be conducted by telephone or email (for those who have email access) to reduce patient participant burden. If requested, surveys will be mailed from the Data Coordinating Center (DCC) to patient participants, and will include a pre-stamped return envelope. Reminders will be sent to non-responders 1- and 2-weeks after the initial survey has been completed. Those who have an email will have the option to receive follow-up email reminders. If the reminders are not successful, surveys will be sent to non-responders via U.S. mail.

Patient participants will receive check-in phone calls and appointment reminders from the study coordinator prior to the three and six month follow-up surveys. In the event that a participant is a no-show for their clinic appointment, she/he will be recruited at their next clinic appointment.

The tailored, patient-targeted activities such as pre-visit web-based portal messages with access to the decision aid and information on the study time demand; will retain patients by maintaining a stream of consistent information. Each site will choose a tailored patient-targeted activity to display information about the study via patient portal, clinic poster, waiting room TV/online kiosk, and paper-based versions of the decision aid.

6 STUDY INTERVENTION

6.1 Study Intervention(S) Administration

Specific Aim 1:

Clinic Personnel Survey

Clinic personnel will complete a formative evaluation during the first six months of the study, receiving a survey to assess their role in the clinic, clinic culture, as well as their perception on the clinics readiness to implement the DA. This survey will be administered to up to 15 clinic personnel per site at most and will last for 20 minutes. Clinic personnel will receive an email with a link to complete the online Qualtrics survey. Reminder emails will be sent to non-responders 1- and 2-weeks after the initial survey email.

Key Clinic Personnel Interview

The PI/ research coordinator at each site will identify six to eight clinic personnel that are well versed in the flow of the clinic, and will be able to assist in sustaining the intervention once the study is completed. The clinic personnel will view a brief video animation about the value and content of the DA. Semi-structured interviews will be administered to these six clinic personnel over the phone or in person, to explore perspectives on practice needs, and barriers or facilitators to implementing the decision-aid. These interviews will last no more than 60 minutes.

Note: These should not be the study coordinator. Acceptable clinic personnel would be the clinic champion or nurse supervisor.

Before interviews begin, the study team will pilot test the clinic personnel survey and semi-structured interview guides with clinic personnel other than those already chosen for the final interview. The guide will be edited based on feedback from this pilot testing. The study team will take into consideration the following when developing the interview guide for Specific Aim 1:

- Time staff has available for the interview.
    - Most staff, especially physicians or nurses, will not have the entire hour to devote to the interview. The study team will develop a shorter semi-structured interview guide, made up of questions that address key factors for Specific Aim 1 to use in special cases like this.
- Are the interview questions clearly worded? Are any of the questions vague or unclear?
- Interview questions ordered in a way that makes sense? Do any of the questions seem repetitive?

Clinic personnel who agree to participate will be sent the interview questions one-week in advance of the scheduled interview. All clinic personnel (even those who will not be interviewed) will receive an electronic copy of the decision aid and be trained on its use through an educational video. The video will explain what the decision-aid is, as well as suggested methods on how it can be administered to patients in the clinic.

Clinic Personnel surveys will be completed electronically via Qualtrics® (Seattle, WA) and stored for analysis. The semi-structured interviews will be administered over the phone, recorded, and transcribed for analysis in NVivo®.

Specific Aim2: Prior to each site implementing the decision aid; standardized capacity-building activities will be initiated. These activities are as follows:

- Education: A series of 60-minute seminars including all 16 clinics that educates clinic personnel about the decision aid includes its purpose, contents, and supporting evidence.
- Training: A series of webinars, offered 1-2 months after each sites formative evaluation, that describes the clinic-specific findings of the formative evaluation, reviews the implementation strategies available to the clinic (both standardized and tailored), and jointly identifies the preferred strategies for the clinic.
- Technical Assistance: On going, ad hoc technical support on the use and maintenance of the iPad (e.g., trouble launching the DA, problems navigating screens).
- Clinic Champion: - Designated member of clinic who is dedicated to supporting, marketing, and driving implementation of the DA in the clinic.
- Refresher Training Course: A webinar conducted every six months or as needed that describes the

implementation strategies, common barriers being confronted across the 16 participating clinics, and shares best practices of how these strategies are being deployed across the 16 clinics to sustain the intervention.

Tailored Implementation Activities

Sites will also have the option to choose from recommended Tailored Implementation Activities. These strategies are clinic-targeted and patient-targeted activities designed to stimulate participant recruitment and retention. Sites will choose either activity that is most relevant for implementation of the DA at their clinic and we anticipate that some sites will choose both activities. At the end of the study, all sites will be reviewed to determine with strategies were used throughout the duration of the study.

Clinic-targeted Activities:

- DA reminder in patient intake process
- Audit and feedback
- Team huddles/clinic meetings

Patient-targeted Activities

- Pre-visit web-based portal messages with
    - Access to decision aid via a link
    - Information regarding the study time demand
- Pre-visit delivery of paper-based version of decision aid
- Clinic poster about decision aid
- Decision-aid information through the waiting room TV/online kiosk

The DA will be given to all patient participants that meet the eligibility criteria during their regularly scheduled lupus clinic visit. Before reviewing the decision-aid, patients will view a short educational video on the purpose and use of the decision-aid. Questionnaires and the DA will be administered on an iPad, and questionnaires will take no more than 30 minutes on average, to keep responder burden low. Three and six-month follow-up questionnaires will be administered via phone, mail, or at the regularly scheduled clinic visit per the patient participant preference, and will last no more than 15 minutes.

In the event clinic personnel transition to a different position or leave the organization, they will be given a Clinic Personnel Exit interview* to assess the reason for departure, their view on the dissemination of the decision-aid into normal clinic flow, and the sustainability for future use.

<u>Aim 2 Clinic Personnel Survey</u>

Clinic personnel will complete a formative evaluation at 0-, 6-, 12- and 24- months of the study, receiving a survey to assess *acceptability, appropriateness, feasibility, success, and permanence of the DA*. This survey will be administered to up to 15 clinic personnel per site at most and will last for 10 minutes. Clinic personnel will receive an email with a link to complete the online Qualtrics survey. Reminder emails will be sent to non-responders 1- and 2-weeks after the initial survey email. All outcome will be measured on a Likert-type scale from (strongly agree = 1) to (strongly agree = 5). For composite outcomes, mean scale scores will be computed.

Specific Aim 3: Semi-structured interviews will be administered to the clinic personnel interviewed as part of Specific Aim 1, as well as 2 patient participants per site from Specific Aim 2, over the phone to reduce patient/clinic personnel burden. The interviews will be done by the UAB study team lead by Dr. Herald, in collaboration with Drs. Hall and Qu, coordinated by Ms. Tatum and Ms. Green. These interviews will be conducted within 45-60 minutes and transcribed to

analyze the effectiveness of implementing the decision aid in a normal clinic setting and sustainability facilitators and barriers. These responses will develop the step-by-step implementation guide for future use in a clinic setting.
The study team will take into consideration the following while developing the interview guide for Specific Aim 3:

- Turnover in clinic personnel*
    - There may be turnover in clinic personnel whom were interviewed for Specific Aim 1. There will be specific questions in the interview guide for Specific Aim 2 to account for this.

Study coordinators will be interviewed every six months to assess the implementation and sustainability of the DA in the clinic flow. This survey will be given over the phone to one study coordinator per site every 6 months, lasting no more than 30 minutes per site. These interviews will be recorded and transcribed for study records; any actionable concerns will be decided upon in the following weekly study conference call.

6.2 Measures to Minimize Bias

The observational study design explicitly incorporates varied context and baseline capabilities between the practices. This approach could lead to potential selection bias issues. To minimize the potential for selection bias, we have recruited clinics with varied characteristics both private and academic; general rheumatology and lupus clinics to implement the DA from a wide-range of geographical areas.

6.3 Implementation Strategy Fidelity and Adaptation

Study investigators will develop and work with clinic personnel to apply the standardized and tailored implementation activities within the clinic setting. It is expected that strategies will be adapted to suit each clinic's unique context and circumstances. We therefore expect to implement 16 different approaches. We will capture and describe each unique approach and use these findings to inform key outcomes. The periodic check-ins for each site following the Education, Training, and Refresher Training standardized activities will allow study personnel to determine the extent to which the DA has been implemented within clinic flow and processes.

Patient participant study compliance will be measured by completion of all study assessments, including the three and six month follow-up and semi-structured in-depth phone interviews. We will also assess whether or not the patient views the DA at the first visit at baseline and/or requests an electronic or paper copy of the DA (Aim 2).

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 Participant Discontinuation/Withdrawal from the Study

Participants (both patient and clinic personnel) are free to withdraw from participation in the study at any time upon request. Withdrawal will not affect the participant's future medical treatment or relationship with the physician. The participant may also revoke data authorization at any time by informing the study coordinator or investigator. There will be no penalty or loss of benefits owed if a participant decided to not participate.

An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Significant study non-compliance
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant (either patient or clinic staff) discontinuation or withdrawal from the study will be recorded in the study database.

7.2 Lost to Follow-Up

A patient participant will be considered lost to follow-up if he or she fails to respond to multiple contact attempts. The following actions will be taken if a participant fails to return to the clinic for a required study visit:

- The study coordinator will attempt to contact the patient participant (mail, phone call, email).
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant. These contact attempts should be documented in the participant's study file and the recruitment excel sheet.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

This study will be coordinated by the University of Alabama at Birmingham (UAB). All study visits and procedures will be performed at the United States, and at n = 16 sites. At least 35 participants are expected to be enrolled at each site. Enrollment will be competitive between sites.

Participants will be seen according to the details that follow:

Specific Aim 1: Clinic Personnel Survey/Semi Structured Interviews
This Specific Aim will: a) identify clinic staff and patient needs, and b) key contextual factors that inform targeted strategy selected influence implementation effectiveness, and sustainability. It will do so via two data collection efforts:

Clinic Personnel Survey
Up to 15 clinic personnel will be administered an online survey via Qualtrics® to assess their role in the clinic, clinic culture, and readiness to implement change. This will last between 20-25 minutes. Clinic personnel will be emailed a link to complete the survey. An automatic email will be generated in the Qualtrics® system and will go out to all non-responders every 24 hours for 5 days, or until the survey is completed.

Semi-Structured Interviews
Each site PI/ study coordinator will choose 6-8 key clinic staff that will be administered a 45-60 minute semi-structured interview either via phone or in person that will assess stakeholder needs and identify characteristics of the clinics (e.g., policy environment, physician, clinic, patient barriers) that influence DA adoption and choice of the implementation strategy. The interview protocol will be adapted to fit each time range and different key personnel. A link to the brief video animation introducing the decision-aid use and content along with the interview protocol and copy of the decision-aid will be emailed to clinic personnel prior to being interviewed. All interviews will be recorded and transcribed verbatim for accuracy.

Specific Aim 2: Implementation

Patient Baseline Visit
The baseline visit will take approximately 1 hour to complete. All patients with lupus are eligible. The study coordinator will approach patients at their regularly scheduled lupus clinic appointments. Once the potential participant checks in either at a kiosk or with a front desk clerk, they will be made aware of the lupus decision-aid by either the clinic clerk or the study coordinator. The study coordinator will then approach the patient participant and invite them to participate in the study. If a patient participant declines the invitation to participate, the reason will be recorded in the excel spreadsheet. If the patient participant agrees to participate, he/she will be given a non-signature consent form which

explains the study objectives. The patient participant will be given the necessary time to read the non-signature consent form and ask any questions they have to the study coordinator. No signature will be necessary on the consent form. Participants will be required to sign a paper HIPPA form since study coordinators will view limited personal health identifiers (PHI) (medical record number, voice from conversations with physicians). The coordinator and patient participant will be required to sign the HIPPA form, and a copy will be given to the patient participant, as well as being placed in their file.

After the non-signature consent form is given to the patient participant, study procedures will begin and a participant number will be assigned. During the baseline visit, the following procedures will be performed and information will be obtained to determine eligibility to continue in this research study:

- Review inclusion/exclusion criteria
- Date of birth
- Self-reported race/ethnicity

Patient participants will be invited to watch a short informational video on the iPad and review the DA, before beginning the assessments. After completing the questionnaire, patients will complete a W-9 form that allows payment to be processed. Participants will be compensated via a paper check from the Data coordinating center that will take up to 7 business days to be issued, per institutional accounts payable procedures. Patient participants will receive payment ($50) after the initial visit has been completed.
Each patient participant will be reminded of the three and six month follow-up phone calls prior to the visit departure.

Specific Aim 2: Follow-up Patient Participants
We will follow each patient participant from screening for up to six months until completion of the full study (week 26). Unless the subject withdraws consent, the subject will be followed for the full study period and all data will be collected as scheduled. At three and six months post baseline visit, patient participants will be administered a 15 minute survey. Patient participants will receive a $10 payment (via check) from Data Coordinating Center after each survey has been completed. Non-responders will be administered the survey on their next regularly scheduled lupus clinic visit.

Specific Aim 2: Clinic Personnel Survey
Up to 15 clinic personnel, the same clinic personnel as surveyed in Aim 1, will be administered an online survey via Qualtrics® at 0-, 6-, 12- and 24-months to assess their perception of appropriateness, acceptability, success, permanence and feasibility of the decision-aid. This will last between 20-25 minutes. Clinic personnel will be emailed a link to complete the survey. An automatic email will be generated in the Qualtrics® system and will go out to all non-responders every 24 hours for 5 days, or until the survey is completed.

Specific Aim 3: Semi-Structured Interviews
Clinic personnel interviewed for Specific Aim 1, as well as 2 participants at each site (selected by the site PI), will be administered a 45-60 minute, semi-structured phone interview. This interview will identify opportunities for sustaining and disseminating a lupus DA and help to develop a manual that provides a step-by-step implementation guide for incorporating lupus DA into regular clinical visits and care pathways for patients with lupus. This Specific Aim will result in: 1) knowledge of key lessons learned about the implementation process; 2) challenges to sustaining use of the DA; and 3) a manual that provides step-by-step implementation guide for incorporating lupus DA into regular clinical visits and care pathways for patients with lupus**.** Questionnaires will be adapted as in Specific Aim 1 to fit each time range, key personnel, and to account for any turnover in personnel interviewed in Specific Aim 1.

Study Coordinators

Every six months, a study coordinator from each site will be interviewed to evaluate the implementation of the DA and what can be done to improve the use and effectiveness within normal clinic flow. This interview will be administered via telephone. Non responders will be called every 24 hours for five days, or until a response is received.

8.1 Adverse Events and Serious Adverse Events

8.1.1 Definition of Adverse Events (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

8.1.2 DUE TO THE NATURE OF THIS STUDY, THE RISK OF ADVERSE EVENTS IS EXTREMELY LOW. WE WILL REPORT ALL SERIOUS AES ACCORDING TO APPROPRIATE AUTHORITY (PCORI, IRB) USING STANDARD GUIDELINES AND REGULATIONS OUTLINED BELOW.DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

A SAE is any AE occurring at any dose that results in any of the following outcomes:

- Death
- Is life-threatening (places the participant, in the view of the site PI, at immediate risk of death from the AE as it occurred)
- Inpatient hospitalization or prolongation of existing hospitalization (hospitalization is defined as an inpatient admission, regardless of length of stay, even if hospitalized as a precautionary measure for continued observation)
- A permanent, persistent, or significant disability (substantial disruption of the ability to conduct normal life functions). A medically significant AE that may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

Events NOT considered to be **Serious** are:

- Hospitalization for treatment, which was elective or pre-planned, for a pre-existing condition that did not worsen
- Treatment on an emergency, outpatient basis for an event NOT fulfilling any of the definitions of serious given above and NOT resulting in hospital admission
- An event that, had it occurred in a more serious form, might have caused death
- A sign, symptom, or event that is noticeable but easily tolerated.
- An event does not significantly influence performance or prevent the participant from carrying on with their usual life activities.

8.1.2.1 Expectedness

Due to the nature of this study, there are no expected adverse events associated with this study.

8.2 Unanticipated Problems

8.2.1 Definition of Unanticipated Problems (UP)

Unanticipated problems, in general, are defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.2.2 Unanticipated Problem Reporting

Any unanticipated problems will be reported to the appropriate authority (PCORI, IRB) and noted in the study database.

8.2.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

Participants will be informed about unanticipated problems, and study-related results on an individual or aggregate level.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Specific Aim 1: Targeted participants for this Specific Aim are key informants (interviews) and all clinic personnel (surveys). The purpose of this Specific Aim is to identify and quantify clinic and contextual characteristics (e.g., readiness for change, physician attitudes, patient barriers) to inform strategy component selection and influence implementation effectiveness of lupus DA to be evaluated in Specific Aim 2. As such the statistical approach for this component of Aim 1 is largely descriptive and there are no formal statistical null and alternative hypotheses. Specific descriptive statistics are described in the table below andfurther details are provided in Section 9.4. Penetration will be assessed by evaluating the proportion of eligible patients reviewing the DA overall and in each site. Overall rates and 95% confidence intervals will be computed. Patient healthcare utilization outcomes (e.g., inpatient visits and ER/urgent care visits) will be assessed similarly.

Specific Aim 1 Data Collection and Analyses		
Data Type	**Data Collection Type**	**Analytic Methods**
Quantitative	Online & paper survey, Organizational readiness for implementing change (ORIC); Team Learning & Psychological Safety Survey (TLPSS)/ Baseline	Individual & practice level summary statistics Correlation
Qualitative	Semi-structured interviews with key informants/ Baseline	Within-case/clinic thematic analysis of CFIR domains Cross-case/clinic comparison

Specific Aim 2: Targeted patient participants for this Specific Aim are (1) age≥ 18 years with a diagnosis of lupus from participating clinics; for individual-level outcomes, initial analyses will focus on how clinic personnel and patient perceptions change over time. The statistical null hypothesis is the assumption that there is no change over time versus

the alternative that there is a change over time. For the analytic approach we will examine mean levels (total change) and quantify with means (or proportions, as appropriate) and 95% confidence intervals. We will also examine patterns of change (growth trajectories) while controlling for differences between clinics using multivariable models that account for repeated measures and clinic clustering of patients (i.e., generalized estimating equations (GEE) with robust standard errors). Additional analyses may examine by-group comparisons of clinics determined by clinical characteristics (e.g., geographic areas, clinic type, and patient diversity) observed in Specific Aim 1. Any such by-group analyses will be conducted separately. A primary independent variable of interest is the type of strategy used for implementation. Following completion of the study, each sites strategies will be evaluated and sites will be grouped accordingly. A covariate allowing for testing group differences will be included in the multivariable models to assess whether trajectories differ by implementation strategy.

The second component of our evaluation of Specific Aim 2 will use fuzzy set Qualitative Comparative Analysis (fsQCA) to assess effectiveness of implementation strategies for clinic-level outcomes. fsQCA is a case-oriented approach that examines relationships between conditions (similar to explanatory variables in regression models) and outcomes using set theory to answer the question: "what conditions, alone or in combination, are necessary or sufficient to produce an outcome?" For patient-physician communication analysis, question-asking, assertive responses, and expressions of concern, will be coded as patient participation; supportive talk and partnership building by provider will be coded as active physician communication. Further details are provided in Section 9.4.

Specific Aim 3: Targeted participants for this Specific Aim are the same key clinic informants from Specific Aim 1 and 2 patients per clinic from Specific Aim 2. Similar to Specific Aim 1, the analytic approach is largely descriptive and there are no formal statistical null and alternative hypotheses. Specific descriptive statistics are described in the table below. Further details are provided in Section 9.4.

Specific Aim 3 Data Collection and Analyses		
Data Type	**Interview Content**	**Analytic Methods**
Qualitative	Perceived challenges to long-term sustained use of the DA Understand the lessons learned	Within-case/clinic thematic analysis of CFIR domains Cross-case/clinic comparison

9.2 Sample Size Determination

A power analysis for the quantitative portion of Specific Aim 2 was conducted using the following assumptions: (1) 16 clinics and (2) an intraclass correlation coefficient of 0.05. This provided us with a total confidence interval width of 5.3% for 10% of the total clinic population that is administered the lupus DA to a width of 8.1% , if 40% patients are administered the lupus DA. For outcomes on a 5-point Likert scale, the corresponding 95% CI widths for standard deviation of 0.5 and 2.0 on the mean score is estimated to be 0.09 vs. 0.35, respectively. For individual-level outcomes measured as a rate (e.g., # visits/1,000) or as means (e.g., Likert-scale), we anticipate small margins of error. A minimum number of proposed sites (n=16) are needed to comprehensively assess how different implementation strategies are influenced by and interact with different contextual conditions (different geographic areas, clinic type, and patient diversity) to affect implementation effectiveness, and thus, determine the generalizability of the study findings. However, given the proven effectiveness of the DA (original PCORI study), and in the spirit of dissemination and implementation research, we will continue to recruit to our proposed maximum sample size target of 3,000.

9.3 Populations for Analyses

The analysis population for each Specific Aim is below:

Specific Aim 1

- Key clinic personnel who complete the semi-structured in depth phone interview (6-8 staff per clinic)
- Clinic personnel who complete the online clinic personnel survey (all staff, up to 15 per clinic)
- Using administrative records, sites will report the total number of patients viewing the DA and the total number of patient visits during the active study time frame.

Specific Aim 2

- All enrolled participants who complete the baseline visit, as well as those who complete the three and six month follow-up questionnaires
- Clinic personnel who complete the online surveys

Specific Aim 3

- Key clinic personnel from Aim 1+ 2 patients per site who complete the post-study semi-structured in depth phone interview. (6-8 key clinic personnel + 2 patients per site)
-

The protocol population will be all participants who attend all study visits and complete the trial.

9.4 STATISTICAL ANALYSES

9.4.1 General Approach

IDEAL investigators Dr. Larry Hearld, Dr. Allyson Hall, and Dr. Haiyan Qu will oversee all qualitative data management and analysis for IDEAL Data Coordinating Center (DCC). Dr. Szychowski and Mr. Cleveland will oversee all quantitative data management and analysis for IDEAL DCC. The DCC is housed within the UAB School of Health Professions. Questionnaires have been developed and tested before being uploaded into Qualtrics. Data will be entered into the electronic database (Qualtrics) using iPads. The DCC will ensure that the data collected and analyzed for this study are of the highest quality possible, and will be accomplished in part by having thorough edit checks as close to collection in time as possible, and updated as needed to guarantee high quality data through quality control and quality assurance. Edit checks will be reviewed by the statisticians, program manager, as well as other team members on an ongoing basis to evaluate whether any checks need to be added or any existing checks need to be modified. All data will be entered into the IDEAL electronic Data Entry System (eDES; Birmingham, AL) directly using iPads for seamless data management and auditing across the IDEAL sites. All quantitative analyses will be conducted using SAS (Cary, NC) Version 9.4 or higher or R-routines for specialty programs as needed. All qualitative analyses will be conducted with NVivo 12, available through the UAB School of Medicine.

9.4.2 Analysis of the Primary Efficacy Endpoint(S)

Specific Aim 1:

Qualitative: Emergent theme analysis, within each clinic and based on the CFIR domains, will be initially conducted. These themes will be used to identify the preferred implementation strategies for use in a clinic. These within-case themes also will be used to compare and contrast between clinics to identify unique and common barriers to implementation.

Quantitative: Univariate statistics (means, standard deviations) will be used to describe each clinic's learning environment and readiness to implement change. Spearman correlations will be estimated to assess how different aspects of the clinic's learning environment and readiness to implement change may vary across clinics. Similarly, t-tests and one-way ANOVAs will be estimated to assess how the learning environment and readiness to change varies as a

function of clinic characteristics (e.g., location, private vs. academic). Penetration will be assessed by evaluating the proportion of eligible patients reviewing the DA overall and in each site. Simple proportions and 95% confidence intervals will be computed. Patient healthcare utilization outcomes (e.g., inpatient visits and ER/urgent care visits) will be assessed similarly.

The results of the qualitative and quantitative analyses described above will be consolidated to construct a profile or "case study" for each clinic.

Specific Aim 2:

Targeted participants for this aim are (1) age≥ 18 years with a diagnosis of lupus from participating clinics. Objective measures will be assessed in both clinic personnel and in patients. Clinical personnel will evaluate perceived acceptability of intervention measure for the DA, perceived DA implementation success, and perceived DA permanence. All will be assessed on an ordinal scale (strongly disagree = 1) to (strongly agree = 5). Similarly, patients will evaluate perception of DA usefulness, patient satisfaction for the DA, perceived intervention appropriateness measure for the DA, and perceived feasibility of intervention measure for the DA. All of these patient assessments will be measured on a Likert-type scale.
For individual-level outcomes, initial analyses will focus on how clinic personnel and patient perceptions change over time. We will examine mean levels (total change) and patterns of change (growth trajectories) while controlling for differences between clinics using multivariable models that account for repeated measures and clinic clustering of patients (i.e., generalized estimating equations (GEE) with robust standard errors). The second component of our evaluation of **Aim 2** will use fuzzy set Qualitative Comparative Analysis (fsQCA) to assess the effectiveness of implementation strategies for clinic-level outcomes. fsQCA is a case-oriented approach that examines relationships between conditions (similar to explanatory variables in regression models) and outcomes using set theory to answer the question: "what conditions, alone or in combination, are necessary or sufficient to produce an outcome?"
For patient-physician communication analysis, question-asking, assertive responses, and expressions of concern will be coded as patient participation; supportive talk and partnership building by provider will be coded as active physician communication.

Specific Aim 3:

Similar to **Aim 1**, emergent theme analysis within each clinic will be initially conducted. These themes will focus identify the implementation lessons learned by the clinics, including and especially the implementation challenges faced by the clinic throughout the study, and their opinions of the opportunities and challenges to sustaining use of the DA once the study ends. These within-case themes also will be used to compare and contrast between clinics to identify common lessons learned and ideas for how to sustain the DA moving forward.

9.4.3 Analysis of Secondary and Safety Endpoint(S)

The statistical analysis plan will be modified to incorporate analysis of any safety outcomes or secondary endpoints identified after initiation of the study as needed. An unintended consequence of the implementation of the lupus DA will be captured and measured accordingly.

9.4.4 Baseline Descriptive Statistics

Clinical characteristics and patient demographics will be collected. Descriptive statistics will be reported using means and standard deviations (or medians and quartiles) for continuous-type data and using counts and proportions for categorical-type data. For any by-group comparisons, the two-sample t-test (or Wilcoxon Rank Sum test, as appropriate)

will be used to evaluate continuous-type data. The chi-square test of independence (or Fisher's exact test, as appropriate) will be used to evaluate categorical-type data. Statistical significance will be evaluated at a 0.05 level. Descriptive statistics will be presented overall and by groups defined by implementation strategy.

9.4.5 Interim Analyses

No interim analyses are planned at this time.

9.4.6 Sub-Group Analyses

We are planning the following subgroup analyses, if enough data are available. The analysis approaches are described above.

- Clinics with vs. without prior experience with DA,
- Setting, private vs. academic,
- Location, urban vs. suburban,
- Type of clinic, general rheumatology clinic vs. lupus clinic vs. rheumatology/renal hybrid clinic,
- By the language of decision-aid used English vs. Spanish,
- Patient characteristics including the biological variables (age group, sex, race/ethnicity), and
- The proportion of patients with Medicaid/Medicare vs. private insurance
- By presence of renal disease
- By level of education
- By insurance mix (>30% private)

9.4.7 Missing Data and Outliers

The rate of missing values will be evaluated on a variable-by-variable basis. Clinics and/or patients with extensive missing values will be deleted from all analyses. A clinic or patient with a missing value for any variable involved in a specific analysis will be excluded from that analysis only (case wise deletion). There are no plans for imputation of missing values. Theoretical assumptions for all statistical procedures will be evaluated (e.g., evaluation of normality, residual plots, and outlier evaluations). Any outliers will be inspected for data coding and entry errors and they will be corrected whenever appropriate. In the case of true outliers, sensitivity analyses with the specific values removed will be conducted in order to evaluate the robustness of the observed results.
In the event that there is insufficient (or excessive) variation in implementation strategies to create 2 clearly differentiable study groups, alternative definitions of the primary independent variable may be created (e.g., groups determined by number of strategies used or groups determined by percentage of staff trained).

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 Regulatory, Ethical, and Study Oversight Considerations

10.1.1 Informed Consent Process

10.1.1.1 Consent/Assent and Other Informational Documents Provided to Participants

A non-signature consent form will be provided to all participants (both clinic personnel and patient participants). The non-signature consent will describe the study in detail, payment procedures, as well as give participants important contact information for study personnel. Limited personal health identifiers (PHI) may be used (audio recording with physician, etc.), so all patient participants, as well as staff will be asked to sign a HIPPA form, and will be given a copy for

their records. The study coordinator/person obtaining consent will also sign the HIPPA form. A copy of all signed HIPPA documents will be kept in the study binder under lock and key.

10.1.1.2 Consent Procedures and Documentation

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Participants will be asked to read and review the UAB IRB approved information sheet and HIPPA form. The investigator/study coordinator will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the information sheet and HIPPA form and ask questions prior to signing (the HIPPA form). The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate.

The participant will be given the information sheet prior to any procedures being done specifically for the study. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the information sheet and HIPPA form will be given to the participant for their records. The informed consent process will be conducted and documented in the source document (including the date), before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

Clinic staff participating in the study will be informed about the study by their nurse manager/supervisor. A verbal explanation will be provided in terms suited to clinic staff comprehension. Staff will have the opportunity to carefully review the information sheet and HIPPA form prior to signing the HIPPA document. Clinic staff participating in the clinic survey and the semi-structured interviews will be given the information sheet and HIPPA form. Staff will be informed that participation is voluntary and they may withdraw from the study at any time, without prejudice. A copy of the information sheet and HIPPA form will be given to all staff for their records.

10.1.2 Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause, such as documented, clear patient harm. While we are not able to anticipate a patient harm with an educational tool, we will keep the study team aware and observant. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, PCORI and regulatory authorities. If the study is prematurely terminated or suspended, the PI will promptly inform study participants, the IRBs, and PCORI and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the

PCORI, and/ or IRBs.

10.1.3 Confidentiality and Privacy

Participant confidentiality and privacy will be strictly held in trust by the participating investigators, their staff, and their interventions. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. All research activities will be conducted in as private a setting as possible.

Paper and computer files will be safeguarded from unauthorized access and stored in secure locations. Information collected electronically via the computerized decision aids will be stored in a secure central location. Information collected on paper forms will be sent to UAB and stored in a secure location. Computer records of study data will be stored in a central database, controlled by a system of user identification and passwords. Since patient may confide in us regarding sensitive details in the patient-physician conversation audio recordings (Aim 2), these files will be kept controlled by unique usernames and passwords, with access to limited number of study personnel directly involved with the data coding, and data analyses. These data will be handled with extra care, similar to the other sensitive health care information.

Data entered into computerized files will be accessible only by authorized personnel directly involved with the study and will be encoded. Touchscreen computers will be password-protected and encrypted with the state-of-the-art encryption software by the UAB Informatics, so that in case of a loss of a unit, no patient information can be retrieved by anyone.

The information obtained during the conduct of this study is confidential, and disclosure to third parties other than those noted below is prohibited. The results of the research study may be published, but study participant's names or identities will not be revealed.

10.1.4 Key Roles and Study Governance

Principal Investigator
Jasvinder A. Singh, MD, MPH
University of Alabama at Birmingham
FOT 805, Birmingham AL 35294
205-504-9559
jsingh@uabmc.edu

10.1.5 Safety Oversight

Considering the aim of this study is to determine best practices for dissemination of a treatment decision aid). The intervention is one-time and informational, with very low risk of any significant safety issues. This study poses no more than minimal risk to participants and therefore there will be no Data Safety Monitoring Board (DSMB) will be convened.

10.1.6 Clinical Monitoring

No clinical monitoring will be required for this study.

10.1.7 Quality Assurance and Quality Control

Quality control (QC) procedures have been implemented beginning with the Qualtrics® data entry system and data QC checks that will be run on the database once enrollment begins. All personal identifiers collected will be stored on a secure UAB server and backed up nightly. Survey data will be merged with baseline enrollment data to create master

SAS datasets. Logic and range checks in SAS 9.4 (Cary, NC) will ensure identification of data accuracy (see section 9.4). Any missing data or data anomalies will be communicated to the site(s) for clarification/resolution.

10.1.8 Data Handling and Record Keeping

Paper and computer files will be safeguarded from unauthorized access and stored in secure locations. Information collected electronically via the computerized decision aids will be stored in a secure central location; controlled by a system of user identification and passwords. Information collected on paper forms will be sent to UAB and securely stored; data will be handled with extra care, similar to the other sensitive health care information.

10.1.8.1 Data Collection and Management Responsibilities

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All hardcopy source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant enrolled in the study. Data recorded in the eCRF derived from source documents will be consistent with the data recorded on the source documents.

Assessment Data will be captured in Qualtrics®. Since personal identifiers will be collected, all versions of the Qualtrics® electronic data capture tool (housed at UAB) and qualitative data including interview recordings will be stored on secure UAB server that is backed up nightly. Survey data will be merged with baseline enrollment data to create master SAS datasets. Logic and range checks in SAS 9.4 (Cary, NC) will ensure identification of data accuracy.

10.1.8.2 Study Records Retention

Study documents will be retained for a minimum of 7 years after the study completion. These documents will be retained for a longer period, however, if required by the IRB, or PCORI. No records will be destroyed without prior approval from PCORI.

10.1.9 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonization Good Clinical Practice (ICH GCP), or Manual of Operating Procedures (MOOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report protocol deviations. Any protocol violations will be reported to the IRB.

10.1.10 Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies and regulations: The Patient Centered Outcomes Research Institute (PCORI).

This trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers after the completion of the primary endpoint by contacting the Data Coordinating Center at UAB.

10.1.11 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Any actual or perceived conflicts of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed per the policies of the participating academic institutions. The respective academic institution conflict of interest review board has established policies and procedures for all study group members to disclose all conflicts of interest and has mechanisms for the management of such conflicts.

10.2 Additional Considerations

10.3 Abbreviations

The list below includes abbreviations utilized in this template. However, this list should be customized for each protocol (i.e., abbreviations not used should be removed and new abbreviations used should be added to this list).

AE	Adverse Event
CCC	Clinical Coordinating Center
CFR	Code of Federal Regulation
DCC	Data Coordination Center
DSMB	Data Safety Monitoring Board
eCRF	Electronic Case Report Form
eDES	Electronic Data Entry System
GCP	Good Clinical Practice
IC	Informed Consent
IRB	Institutional Review Board
MOOP	Manual of Operating Procedures
PCORI	Patient Centered Outcomes Research Institute
PI	Principal Investigator
PRO	Patient Reported Outcome
SAE	Serious Adverse Events
SAS	Statistical Analysis System
SMILE	Shared Decision Making in Lupus
UAB	University of Alabama at Birmingham

10.4 PROTOCOL AMENDMENT HISTORY

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale.

Version	Date	Description of Change	Brief Rationale
15	6/8/2020	Addition of COVID-19 questions to follow-ups, instructions for virtual recruitment, digital links to follow-ups	COVID-19 Adjustments

10.5 COVID-19 PROCEDURE ADJUSTMENTS

A. Virtual Recruitment Strategy (please note that this may be modified to fit each site's clinic needs, and sites will

send back a modified version to the coordinating center for their records.

COVID-19 modifications to IDEAL study: v1 06/02/2020
Site: _____ Site ID: _____

Due to COVID-19, patients are worried about infection and how lupus might put them at increased risk, and may not want face-to-face clinic visits in 2020 or beyond. In addition, virtual care options with telehealth (telephone or video-assisted outpatient visit) have surged. We therefore:

1) have obtained IRB permission to do 3- and 6-month surveys using text, email or phone (IRB-approved April 2020);
2) added COVID-19 questions to baseline, 3- and 6-month surveys (IRB-approved April 2020); and
3) requested permission to enroll participants virtually (Pending approval as of 06/02/2020)

Following is a list of potential changes to IDEAL enrollment during COVID-19. The details below only note changes that may be needed to continue successful IDEAL implementation. We fully understand that each site is unique and solutions may can change over time. **Please review and modify the proposed changes below for your site and send back to us as soon as possible.**

BASELINE VISIT (In-person)

1. COVID-19 may affect patients' willingness to use touch-pads. If a **patient agrees to use a touch-pad**:
    a. Please adopt a process of sanitizing tablets between patients (and in front of each patient), to make patients confident and comfortable that performing the study on the tablet will not put them at risk of COVID-19.
    b. Provide gloves to patient who wants to enroll in the study; provide masks per clinic standard.
2. Patients' **DOES NOT want to use touch-pads**:
    a. **MOST PREFERRED- Pt Phone:** Text/Email option on patient's phone (preferred since direct survey entry)
        i. Electronic DA: Coordinator sends the lupus DA link to the patient's phone via text or email, watches the patient go through the first few steps until the DA viewing of scenario starts; then patient can view it for a few minutes
        ii. Electronic survey: Patient completes the survey through the link on the last screen of DA; coordinator makes sure they check back with the patient.
    b. **Paper copy of DA plus survey link option**: Please have some DA paper copies and make them available
        i. Paper DA: the lupus decision-aid (**default scenario is B or C**, unless new disease, where it is **A**) Keep them handy in the clinic area. Each patient gets his/her paper copy of the decision-aid, that they view. Ask them to take it home and save it, since you will be asking them to re-review the content at 3 and 6 months.
        ii. Electronic survey: Once the patient completes the paper copy DA, text/email link, ensure they an open and fill the first two fields correctly including patient ID.
    c. **LEAST PREFERRED** - **Paper copy ONLY option**:
        i. Paper DA: Paper copy of the lupus DA (**default scenario is B or C**, unless new disease, where it is **A**)
        ii. Paper survey: patient completes the paper survey in the clinic, hands it to the coordinator, who quickly checks for any missed items. Study coordinator will enter it after patient visit completed.
3. Completion in the clinic is highly preferable rather than the patient taking it home, due to COVID-19 issues: Mailing is a challenge and remembering to complete the survey is another challenge. Also, if this step is not completed, patients can not be paid $50, which can really lead to trust issues and misunderstanding. Please have patients complete it in a safe area in the waiting room or the patient clinic room, whichever is most convenient/safe.
4. Consider using tablet stands for viewing the decision aid to reduce the perception of risk of COVID-19 by using the tablet computers. The tablet stand also should be sanitized between patients in front of each patient starting the study.
5. Recording: just as previously, since this does not require patient touching the tablet.

BASELINE VISIT (Virtual) (UAB IRB approval STILL PENDING)

1. Virtual patient consent and enrollment
    a. Look-up the provider's telehealth list in the EHR 2-3 weeks prior to the clinic day
    b. Find people with telehealth eligible for IDEAL
    c. Ask the provider which scenario is appropriate if patient agrees to participate (or choose B or C as default).
2. Study coordinator asks the patient on the phone if they are interested, and if the coordinator can send them information to review.
3. Send the consent form/information sheet to patient virtually via phone/email and confirm the receipt of the consent form.
4. Study coordinators will have a reminder phone or video call (per patient preference) at least 1-week prior to the visit to:
    a. make sure that the patient understands the study, is providing an informed consent to participate in the study and that he/she has had the opportunity to ask any questions.
    b. guide the patients to the link where the lupus decision-aid aid (educational tool) can be viewed by the patient remotely on their phone, touchpad or a computer, per patient preference.
    c. Confirm that patient is able to click on the link and see the decision-aid (see details on next page under the title: **Subject: Dr _____ - Lupus Survey (Page 3)**
    d. When the DA viewing ends, the survey completion link is on the last page. Remind the patient of this.
    e. Schedule a follow-up call for later that day or the next day to follow-up for trouble-shooting or hear about their experience (de-brief): whatever we learn with the first few patients will make the process better quickly
5. Study coordinators complete the follow-up call within 24-hours and let *candacegreen@uabmc.edu* know so she can check the data capture. This also helps the site process patient remuneration without delay.
6. Study coordinator will inform patient's lupus care provider prior to their virtual visit (the day of the visit or 1-day before the visit) with email and paper note on the schedule (or both), that the patient has viewed the lupus decision aid at home, so that any questions related to the information can be addressed during their virtual visit. For sites that allow the recording of the telehealth visits, it will be recorded for IDEAL. We will have to figure out how site can securely send the recording to us.

3- and 6-month VISIT = Virtual Visit via phone with study coordinator or self-directed web-based survey **(Exception: if patient is in clinic within 4 weeks prior to 3- or 6-month visit, complete it during clinic visits)**

1. Phone call: Call and complete the survey as previously on the phone. **PRO**: you are done in 20-25 minutes once you reach a patient, and there are only 2 follow-ups in a 6-month period.
2. Study coordinator calls the patient and asks them if they prefer to complete the survey themselves:
    a. Send the anonymized link (Provided by UAB) in real time to the patient via phone/text reminder/web link during the phone call with the use of speaker phone by the patient
        i. make sure they have a link on their phone or email that works
        ii. Help the patient put in the patient ID and site location ID as follows, so no room for error exists- these are forced responses, so survey will not get "submit" without these and we won't know who filled it, if missed:
            1. Click "**____ month survey"**
                a. Site Location ID: **UCLA-04**
                b. Patient ID: **04_____**
                c. Answer the remaining questions
        iii. Urge the patient to continue and complete the survey when the phone call ends, so that they don't lose the link and get frustrated
3. Study coordinator to follow-up with the patient via text or email: ask them if they completed and if they had feedback about the process

4. Study coordinator emails *candacegreen@uabmc.edu* with patient ID and day of completion within 24 hours to check the completion of each patient survey. Please also send aggregate weekly log as previously noting in-person versus self-directed web-based survey completion

Subject: Dr _____ - Lupus Survey

Hello _____,

My name is _____, and I work with Dr. _____ at UCLA Rheumatology. I hope that you have been staying healthy and well.

I am e-mailing you in regard to a research study that you are currently participating in, IDEAL (Implementing the Decision-Aid for Lupus). At one of your recent rheumatology appointments, you reviewed a decision-aid for lupus and completed a survey.

This study is following patients three and six-months after their initial review of the lupus guide. We are interested in your views and opinions of this guide as well as your experience at our clinic, and would greatly appreciate your timely response to this survey. You will be **compensated $10** for completion of this survey.

Instructions for Completing the Survey:

1. Please go to the following link (*http://www.thelupusguide.com/*)
2. Click "**Next**" under "Coordinator Begin Here"
3. If you are currently experiencing a lupus flare, choose "**Real Flare**"
    a. If you *are not* experiencing a lupus flare, choose "**Hypothetical Flare**"
4. Depending on your language preference, choose either "**English**" or "**Spanish**"
5. On the following page, click "**Click here"** to view the decision aid

    Steps 6-7 are optional

6. Click **"Guide ____"**
7. After you have finished reviewing the decision aid, repeat steps #1-5.

8. Click "**____ month survey"**
    a. Site Location ID: **UCLA-04**
    b. Patient ID: **04_____**
    c. Answer the remaining questions
9. **Please let me know once you have completed the survey by responding to this e-mail**

You can also complete the survey in the following ways (let me know if you prefer any of the options below):

1. **Telephone**
    a. Take the survey over the phone (please provide the best phone # to reach you at)
2. **E-mail**
    a. Receive the survey via e-mail as a PDF
    b. Print and fill out with pen/pencil, and scan back responses to *Put your Email here*
3. **Mail**
    a. Receive a paper copy of the survey in the mail (please provide current address)
    b. Fill out with pen/pencil, and scan back responses to *Put your Email here*

Thank you for taking the time to view this e-mail. Let me know if you have any questions at all.
Thank you again, and stay well!

BLUE SKY ASPIRATIONS for the FUTURE for which resources do not exist, but we will target small grant mechanisms to do this while IDEAL is underway: (1) Develop a free downloadable phone app version of our lupus decision aid, for virtual or regular clinic visits; (2) increase patient compensation at FU visits from $10 to $20.

B. Updated QA/QI: Sites will receive an excel sheet with the patient IDs of those that are in window, due soon, and past window for 3 and 6 months. Sites will receive this sheet every 2 weeks, and are expected to send these back to the coordinating center with notes on completions within 5-7 business days.
C. Updated 3 and 6 Month Follow-Up Surveys: Both 3 and 6 Month surveys were updated with IRB approved questions that ask patients about their attitudes towards COVID-19 and how it has affected them. Sites will be sent a copy of this new survey with the additional questions highlighted.
D. Alternative Follow-Up Methods: Coordinators may share the following links with participants via email as an alternative way to complete the survey.

E. Lupus DA Website: *www.thelupusguide.com*

3-month link: https://uab.co1.qualtrics.com/jfe/form/SV_b2YxLZ271PFl0yN
6-month link: https://uab.co1.qualtrics.com/jfe/form/SV_9meJLTcpRNyZH93
Intervals it is ok to call a patient for each time point are below:
3 months
Min: 61 days
Max: 150 days

6 Months
Min: 151 days
Max: 356 days

If 3-month past due date is 151 days or over, complete this survey as 6-month and mark with a note in the 3-month excel sub-sheet as “permanently missed for 3-months, completed as 6-month”.