Mass General Brigham

Breaking Implicit Bias Habits: An Individuation Pilot to Promote Equity in Rheumatic Disease Care

Detailed Protocol
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Intervention/Interaction Detailed Protocol

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For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.

1. Background and Significance

Black individuals in the U.S. receive less effective care than White individuals for most diseases and socioeconomic and racial/ethnic disparities in chronic disease care quality are pervasive.[1-2] Manifestations of structural racism, including stereotyping, prejudice and discrimination at the interpersonal level, perpetuate these disparities.[3] Implicit bias is defined as "prejudicial attitudes and stereotypical beliefs about a particular social group" that are "activated spontaneously and effortlessly" and frequently result in discriminatory behavior.[4] Nationwide research has repeatedly shown that the majority of non-Black physicians exhibit an implicit preference for White patients relative to Black patients when providing care, paralleling racial attitudes of the U.S. population.[5,6] A study by co-I Hagiwara et al. demonstrated associations between mild-to-moderate provider racial implicit bias and poorer communication, patient reactions and perceptions of recommended treatments.[7] Physician bias regarding patients' socioeconomic status (SES) has been less extensively explored, but has also been shown to impact clinical decision making.[8-10] The majority of studies conducted among healthcare professionals demonstrate significant associations between higher provider implicit bias and lower quality of care.

Specifically, amongst individuals who suffer from systemic rheumatic diseases, racial, ethnic, and socioeconomic disparities have been repeatedly demonstrated. These disparities have been partially attributed to comorbidities, polypharmacy, genetics, or inadequate access to care, yet these constellation of factors do not fully explain the degree of disparities that exist.[11-16] In a study of rheumatoid arthritis (RA), Black vs. White patients were more likely to receive older, conventional disease-modifying antirheumatic drugs (DMARDs) without concomitant biologics (bDMARDs), and were overall less likely to receive any bDMARDs.[17] Lower SES individuals were

more likely to receive corticosteroid monotherapy without standard-of-care DMARDs compared with higher SES individuals.[18] Across Brigham and Women's Hospital (BWH) and Massachusetts General Hospital (MGH), in preliminary analyses (IRB Protocol 2020P003838, Exploring bias in medication prescribing, use and referrals among patients with rheumatic and musculoskeletal conditions), among patients with gout seen in the last 2 years, Black patients were less likely to receive urate-lowering therapy (ULT) compared to White patients (43% vs. 51%) and Medicaid beneficiaries were less likely than Medicare beneficiaries (34% vs. 56%), despite minimal copayments regardless of insurance. Among RA patients, we also observed higher percentages of corticosteroid use among Black vs. White patients, and among Medicaid vs. Medicare beneficiaries, and lower percentages of concomitant methotrexate + bDMARD use among Black vs. White patients. At BWH, among 128 patients with SLE, 25% reported experiencing discrimination[19] and high vs. low discrimination was associated, on average, with 3.5-point higher SLE disease activity scores (p=0.004) after adjusting for age, race/ethnicity, education and insurance status (IRB Protocol 2016P000726, Understanding the role of psychosocial factors and disease activity on medication use among patients with lupus).

While patient preference and perceived discrimination during encounters have been implicated in the receipt of substandard rheumatic disease care for Black compared to White patients and for Medicaid beneficiaries, interventions that address the contribution of provider bias have not been conducted.[20-24] Provider-patient communication is an important pathway by which provider implicit prejudice and stereotyping manifest, and can erode patients' trust in their providers and in the healthcare system.[4,25] Most interventions to reduce provider implicit bias in the healthcare field aim to raise provider awareness of their biases with the hope that this translates into behavior change. <u>However, research has shown that educating providers about their own implicit biases through trainings is insufficient to break prejudice or stereotyping habits, or the discriminatory behaviors that result</u>.[4] One intervention conducted among psychology students resulted in long-term implicit bias reduction using a "prejudice habit-breaking intervention."[26] One component, individuation, is easily delivered within a busy clinical context, and can be incorporated into provider-patient communication, the key pathway by which bias is channeled. Individuation prevents stereotyping (a "cognitive shortcut") by obtaining specific information about members of a social group to facilitate evaluation based on personal characteristics rather than group attributes.[27] To our knowledge, no provider-based interventions have tested individuation strategies.[28] The goal of this pilot is to test the efficacy of an individuation-based intervention among rheumatologists and racially discordant patients at two large, multisite practices to improve racial and SES equity in receipt of high quality care. The primary aim is not to reduce provider bias, but rather to reduce <u>*the reliance on*</u> implicit bias in care decisions for Black and lower SES patients to lessen the impact of structural racism and inequality on care.

2. Specific Aims and Objectives

Aim 1. To test the efficacy of a real-time, provider-based individuation intervention to improve the receipt of high-quality rheumatic disease care among Black and lower SES individuals. *Hypothesis 1: Black and lower SES patients of providers randomized to the individuation intervention will achieve higher quality metric scores compared to patients of providers without the intervention.*
To accomplish this, providers randomized to the intervention arm will be asked to determine a set of questions that will help them uncover several unique "facts" about their patients. For example, questions about their patients' hobbies, their daily routine, their family members (e.g., grandchildren), pets, etc. The concept behind this is that understanding these aspects that make each of their patients unique will reduce provider reliance on stereotyping. Patients actively enrolled in this study participating in Aim 2 (audiorecorded encounters), as well as other patients seen by enrolled providers who meet inclusion criteria during the study period who did not opt out of Aim 2, will all be included in de-identified chart review to examine quality of care related outcomes of interest by provider study arm.

Aim 2. To determine the effect of the individuation intervention on provider-patient communication, adherence, provider trust and care satisfaction. *Hypothesis 2*: *Providers randomized to the individuation intervention will exhibit less implicit prejudice in their communication compared to providers in the control arm; patients in the intervention arm will report greater trust, satisfaction, and adherence.*
To accomplish this, the provider-patient encounter will be audiorecorded and then aspects of communication that have previously been associated with implicit bias (e.g., physician-to-patient talk time ratio, physician word use (number of first-person pronouns, and number of positive and negative emotion-related words, divided by all words in the interaction) and total length of interaction will be assessed. In addition, surveys will be administered regarding trust, adherence and satisfaction, which have also been previously associated with implicit bias in provider-patient communication.

3. General Description of Study Design

We will conduct a cluster-randomized controlled trial. The clusters are 20 rheumatologists at multisite BWH and MGH-affiliated clinics. Rheumatologists will be stratified by hospital and by gender and randomly assigned. Ten rheumatologists will be assigned to the intervention arm and ten to the control. Assessments will be conducted for 8-10 patients per rheumatologist (max 100 patients total in each arm, 200 total). Randomization will be stratified by BWH and MGH Rheumatology main campus hospitals (MGH or BWH/ Faulkner (FH)) and their rheumatology satellite clinic sites, and by provider gender (male or female). Study schema is included as an attachment.

In addition to the 200 SLE, osteoarthritis, and inflammatory arthritis patients including RA who will be studied directly, we also will examine the medical records of patients with inflammatory arthritis, osteoarthritis, or SLE in the practices of the enrolled providers seen during the same study period.In addition to the chart review of patients who meet the inclusion criteria of less than 2 visits in the past year, we will perform a secondary analysis of all patients who may have been seen greater than 2 times in the past year as we anticipate a spillover effect from the intervention and would like to study

this. Patients who were approached to participate in the audiorecorded component of the trial and declined will not be included in this medical record review. We will have no direct interaction with these patients. Most medical records we will review will be for patients of enrolled providers who we had no direct interaction with. The goal of this chart review component is to more broadly examine the impact of the intervention on the quality measures described in Table 1 below, beyond those individuals who will have their encounters audiorecorded. In addition to allowing for a larger sample size for analysis, it also will allow for analyses that may not be influenced by the act of recording an encounter (e.g., possibly, due to the recording, care may be somewhat different from other patients in each providers' practice and this will allow us to capture both). For quality metrics that would only be a onetime screen or once every few years, we will review prior records to see if they were eligible for those outcomes (such as receipt of vaccinations).

4. Subject Selection

1. Providers

1A. Recruitment: Rheumatologists at MGH and BWH/FH will be recruited via email and will be given a fact sheet that outlines the study. Announcements will also be made at MGB rheumatology grand rounds. BWH site physician recruitment will be led by BWH rheumatologist and PI Candace Feldman and MGH site physician recruitment will be led by MGH rheumatologist and Clinical Director Sara Schoenfeld. Faulkner site recruitment will be led by site-PI Dr. Derrick Todd.

Table 1: BWH and MGH rheumatologist demographics

	BWH	MGH
N	47	27
Age<50- %	64	81
Female- %	57	44
Black- %	4	0
White – %	72	74
Asian- %	23	26
Hispanic- %	4	4

1B. Inclusion/Exclusion Criteria: Providers will be male or female adult rheumatologists with ≥1 clinical sessions/week at BWH/FH or MGH rheumatology clinics. We will aim to include a range of provider ages and years in practice. Analyses among Black providers will be exploratory because the focus is on racially discordant interactions, and because of small sample size, however we will not exclude any provider based on race/ethnicity. Drs. Feldman, Todd and Schoenfeld (and their respective patients) will be excluded from this study.

2. Patients

2A. Identification: We will identify patients with systemic lupus erythematosus, osteoarthritis, and/or inflammatory arthritis including rheumatoid arthritis, who are scheduled to see the enrolled providers from BWH/FH and MGH rheumatology main hospital clinics and their rheumatology satellite clinic sites. We will do this using a variety of methods including RPDR, EDW and EPIC searches and chart review. We will exclude any individual who has opted out of research and not contact them. Searches will be conducted by research assistants and supervised by the PI and Co-Is.

2B. Inclusion/Exclusion Criteria: We will include male and female patients of the participating providers who are able to provide consent, English-speaking, ≥18 years old, Black or African American or insured by Medicaid/Mass Health (as a proxy for low socioeconomic status), have a diagnosis of SLE, osteoarthritis, or inflammatory arthritis

including RA (or referred to rheumatology because of high suspicion for these conditions), and have been seen ≤2 times in the past year by the provider. In the past two years, there were >7,400 patients with systemic rheumatic conditions at BWH and >5,600 at MGH; 15% were Black or insured by Medicaid at BWH, 12.4% at MGH. We will exclude patients from the audiorecorded component who are incarcerated or unable to consent. We will exclude any patient from our searches who has opted out of research. If a patient declines to participate in the trial, we will not include them in the medical record review cohort either. However, if a patient of an enrolled provider does not decline participation in the audiorecorded component or is not approached for the audiorecorded component and meets our inclusion criteria, they will be included in our medical record review, along with patients who consent for participation in the audiorecorded component.
2C. Recruitment: Patients who did not opt out of research will be recruited directly via patient gateway and/or mailed letters sent ≥1 week before their scheduled appointment. Patients who do not opt-out will receive a phone call two days before their scheduled appointment and then again one day before their scheduled appointment (if they could not be reached 2 days before) to discuss the study and to conduct the prescreening. This will be conducted by a research assistant. If a patient has been contacted by the study staff and suggests interest in participation but cannot be consented remotely, they will be approached at the time of their visit. We will not ask for provider permission to contact each of their identified patients. We will instead ask providers to consent as part of the primary consent form to participate in the recording of the patient-provider interaction for any patient of theirs who consents to participate in the study. Since our goal is to recruit patients who are less well-established with their respective providers (≤2 visits in the past year), providers may not know the patients well enough to determine whether they should be invited to participate. Moreover, our hope is to better understand and intervene upon potential provider bias and by asking providers to select which patients should/should not participate, we would be introducing additional bias and may exclude patients at risk for experiencing the greatest degree of bias.

The PI will conduct ongoing monitoring of patient responses to ensure that the selection criteria are identifying the right patients. All complaints about this method of recruitment will be submitted to the IRB as an other event.

5. Subject Enrollment

1. Prescreening: There will be no prescreening of providers. Prescreening of patients will occur either prior to the visit during a phone call or at the time of the visit before the encounter if the potential participant is unable to be reached by phone. Please see the prescreening script for details.

2. Informed consent: We will obtain informed consent from providers and patients participating in the audiorecorded component of the pilot study for all providers who agree and for all patients who pass the prescreening as indicated in the script. We will

provide sufficient information to the prospective subjects about the nature of the study and their rights. Conversations about the informed consent process will occur by phone, by MGB zoom/Microsoft teams, or another MGB-approved videoconferencing platform, or in person. We will use REDCap eConsent using a Partners approved video platform or, we will do this in person either with REDCap or a paper form, depending on participant preference. The study staff will be present (either virtually or in person) for the consent process and will obtain either written or electronic informed consent from the participant using Partners approved REDCap e-consent/paperless consent process, or paper form if in person and the patient or provider prefers. REDCap eConsent will be sent securely using “Send Secure” to participants. The text will be "Please follow the below link to find the consent form. Thank you for your participation."

The consent process will be described as follows:

1) The IRB approved designees will explain the study to the subjects verbally, providing all pertinent information purpose, procedures, risks, benefits, alternatives to participation, etc.) while allowing ample time for the potential subject to ask questions.

2) Following the verbal explanation, the potential subject will be provided with a written informed consent form and will be afforded sufficient time to consider whether or not to participate in the research.

3) After allowing sufficient time for the subject to read the informed consent form and think about their participation, we will answer any additional questions before asking them to sign indicating their agreement to participate in the research.

To minimize undue influence to enroll, we will allow both physicians and patients sufficient time to ask any questions and emphasize that participation is voluntary and would not affect their care or status at MGB. There will be no non-English speakers in this study. There will be no use of surrogate decision makers in this study. There will be no post-consenting procedures for this study. No patients of the study PI (Feldman) or Co-I (Schoenfeld) will be asked to participate in this study.

<u>Timing between consent and start of the study procedures:</u>
A. Patients: Multiple attempts will be made for patients to have >12 hours to decide if they wish to enroll. Letters will be sent either via gateway or by mail >=1 week before their appointment, followed by a phone call (if they did not opt out) two days before. They will be sent the consent form virtually prior to the appointment (>12 hours) if they are able to be reached and can receive it electronically. They will be given the option of going through the consent form with a member of the study team and we anticipate that some participants may feel comfortable signing it without waiting the 12 hours, although they will be encouraged to review it. There will be some patients, who despite all of our attempts, will not be able to be consented prior to their appointment. In this case, we will meet these patients who express interest in the study to review the consent form and if they feel comfortable, they will be asked for their consent (<12 hours) before their appointment so that their visit can be audiotaped, and they can participate. Without this,

we will miss patients who both might want to participate, and also who might be disproportionately affected by bias, because their next visit may not be for another 4-6 months.

B. Providers: All providers will have >12 hours to consent participate in the overall study. However, immediately before each audiorecorded patient encounter, they will be given permission to opt-out of that specific recording. If a physician chooses to opt-out from an audiorecording, the demographic information for that patient will be recorded. The purpose of this is to determine if there may be implicit bias based on demographics in who the providers choose not to have participate.

Once providers agree to participate, they will be randomized to either the intervention or the control arm. They will be stratified by site (MGH vs. BWH/ FH) and gender and then randomized using a random number generator. Providers in both arms will be asked to complete Implicit Association Tests and after, to watch a brief set of freely available educational lessons. Patients will not be directly randomized; they will be in the group assigned to their provider as this is a cluster randomized controlled pilot trial.
Statement about informed consent: We have included significant detail in our informed consent however do not provide in-depth explanations about unconscious bias (beyond stating the term) or the ways in which it may manifest itself in an encounter. In addition, we do not provide exact details about the individuation intervention for providers because we do not want to influence the behavior of those randomized to the control arm, and for patients because we want it to feel like an organic part of their encounter. We believe that the intervention (a strategy to help providers get to know their patients a bit better) is no more than minimal risk and that the absence of this specific level of detail in the consent form does not reduce the integrity of the consent or mislead participants.

6. STUDY PROCEDURES

1. Providers
Providers will be recruited and those who consent will be stratified by gender and site and randomized to the intervention or control arm. All providers in both arms will be asked to complete demographic surveys (either paper or on REDCap (with link sent using “Send Secure with the text "Please follow the below link to respond to the survey questions. Thank you for your participation.") and four Implicit Association Tests (IATs). Two of the tests assess biases related to race and two parallel tests assess biases related to socioeconomic status. As this is an interactive tool, we have instead attached the exact terms and instructions that will be used as an attachment. For each of the IATs, providers will be presented with a screen that has either the “cooperative” or “not cooperative” or “good” or “bad” linked with either “Black” or “White” for the race IATs and linked with “rich” or “poor” for the SES IATs. Providers will be prompted to, for example, click left for a bad term or photograph of Black individual, and right for a good term or photograph of a White individual, and then this will be reversed. The same will occur for the SES terms. IATs are standardized, well-accepted tools for measuring implicit bias (https://implicit.harvard.edu/implicit/takeatest.html). Millisecond

software/Inquisit web will be used to administer the tests because it allows for assessment of reaction time for correct classification, which is essential to IATs. Random IDs will be created using RedCAP or Qualtrics that are different from the participant IDs and will be stored on Millisecond/Inquist without any identifiable information. All identifiable information will be stored within the MGB Firewall on RedCap. After providers take the IATs and complete the baseline demographics form (under attachments), both arms will be given the link to freely available brief unconscious bias training module (https://stanford.cloud-cme.com/course/courseoverview?P=8&EID=20775). This module has been approved by the MA Medical Society and is eligible for CME, which can be applied towards the unconscious bias training CMEs required for MA medical license renewal as of June 1, 2022. Upon completion of the unconscious bias module, providers in the intervention arm will meet with study team members to discuss their "individuation" countermeasure intervention and to view the brief presentation with a study team member about individuation. Providers will be given a choice of several individuation-related questions: "How do you spend a typical weekend day?", "How do you spend a typical weekday?", "What is your priority related to your health?", "What are your hobbies/things you enjoy to do in your free time?" and "Can you describe something about yourself that you think makes you unique/different from other people?" to better understand the unique characteristics of each patient. The goal is that this will overcome the physicians unconscious stereotyping and allow them to see each patient as an individual as opposed to as a member of a certain racial or socioeconomic group. Once the provider decides on his/her choice phrases from the above list, the research team will assist with the development of a smart phrase (also called "dot phrase") to allow them to incorporate this into a note. Once a week, providers in the intervention arm will receive an email reminding them to incorporate this question and the documentation into their clinic notes (see attachment of "Provider Reminder Email Script."). We do not anticipate that these questions will include any answers that will place the research subjects at risk, but rather will allow their provider to get to know them better. This documentation will both allow for providers to be reminded of these individual characteristics at a later visit, and also allow the study team to review the notes to determine uptake of the intervention.

≥1 month after providers take the IATs, we will begin the process of recording 8-10 provider-patient interactions within each providers' practice. This will occur at BWH or MGH Rheumatology main campus and satellite clinic sites. Providers will also be immediately informed before a patient encounter that will be recorded and will have the opportunity to decline. We anticipate encounters to last between 20-40 minutes. The vast majority of rheumatology outpatient encounters include only the provider and patient but if any other person is in the room (e.g., an observing medical resident), they will be asked for their permission as well. To record, a digital voice recorder (this one, or an equivalent from the MGB approved Staples vendor: https://www.staples.com/Gpx-Pr047b-Digital-Voice-Recorder/product_2699228) or an MGB-encrypted iPad will be used (placed in the room by a research team member with both patient and provider aware, and collected immediately following the encounter), and all data will be transferred to the project-specific MGB secure drive at the end of each day and then

deleted from the device. For the iPad, the recording will be saved directly onto MGB Dropbox (and the MGB Dropbox app will also be used for the recording). These files will be transcribed verbatim using an MGB-approved vendor and all identifiable information will be removed. After 6 months, which is our estimate for recruitment time, providers will be asked to repeat the IATs. After completion of the study, providers will receive a one-time $50 gift card or e-check.

2. Patients
Patients who consent to participate will be asked to have one clinical encounter with their provider recorded (preferably the next appointment) and then to complete a set of baseline surveys following that encounter including demographics, social determinants of health, everyday discrimination experiences, satisfaction with care, patient trust in the medical profession, patient perception of care centeredness and medication adherence. Surveys can be completed either via REDCaps via a link sent securely to the patient, or on paper forms (and then will be entered into REDCap by our study team). We will also assess medication adherence again 3 months after the encounter using a survey or a brief phone call, and over the 6-month period using the proportion of days covered data now available in the EMR. Patients will receive a $30 gift card or e-check once the surveys are completed. We will also collect data from the patients' charts. These data include: demographics, social determinants of health, comorbidities/diagnoses, quality metrics related to their rheumatic disease, lab results, preventive care use (including immunizations), healthcare utilization (including ED visits, hospitalizations, outpatient visits and appointment no shows), medication use (including use of contraception as a quality metric), and medication refill data (proportion of days covered, available in the EMR) over the 6 months following the date of the recorded encounter. We will review the note from the date of the encounter and determine whether the individuation statement was documented in the intervention group.

3. Chart reviews
We will examine the charts of patients with lupus, osteoarthritis, or inflammatory arthritis seen >1 time by enrolled providers in both the intervention and control arms during the 6 months following provider enrollment, beginning ≥1 month after the date the provider takes the IATs. As indicated above, we will not obtain informed consent for patients of consented providers who will not be audiorecorded but whose charts will be reviewed. Patients who were reached and invited to participate in the audiorecorded encounter and surveys and did not consent or opted out of participation when approached will not have their chart reviewed. Patients who were not approached, or who were sent letters but could not be reached by phone or in person and did not opt out and are seen during this time frame by providers who are part of this study, may have their charts reviewed. We plan to collect demographics, social determinants of health, comorbidities/diagnoses, quality metrics related to their rheumatic disease, lab results, preventive care use (including immunizations), healthcare utilization (including ED visits, hospitalizations, outpatient visits and appointment no shows), medication use (including use of contraception as a quality metric), and medication refill data over the 6 months following the date of the recorded encounter. We will also see if any of the individuation

statements (smart phrases) were used for patients not specifically enrolled in the intervention (spillover from practice changes by the provider).

4. Return of results
For providers, all data will be deidentified and analyzed in aggregate. Unique de-identified codes will be used for the provider IATs that will be linked with the provider-patient recordings. The PI and Co-Is will be blinded and only see de-identified data which will be used for analyses. This is to reduce any risk to the providers reputation or employment. One experienced, trained research assistant will be able to link the data to identifiers should an unexpected situation arise and make this necessary however the PI and Co-Is will be blinded in order to ensure that the reputation of providers in their practices is preserved. Results in aggregate will be presented in an end-of-study Grand Rounds to both the BWH and MGH rheumatology divisions (there is a combined grand rounds). The title of this grand round swill be “Presentation of Findings from Breaking Implicit Bias Habits Intervention Study.” We will submit this presentation to the IRB for approval prior to the Grand Rounds. If we do find examples of implicit bias and explicit discrimination, we will work with MGB equity leadership in this area, who are aware of this study and have been part of these discussions (including Dr. Tom Sequist, Carla Carten and Jarrod Chin) to determine the best Division-wide training tools to use to address this need.

For patients, data will also be de-identified for analyses and de-identified codes will link survey responses with the provider-patient encounter. However, we will be able to link survey scores back to patients and after the completion of the 3-month adherence study, we will provide them with a score report indicating what their scores on each of the respective surveys mean. A sample score report will be submitted as an amendment once we have analyzed surveys and have determined the best way to present these data.

5. Outcomes.

The primary outcome is documented receipt of high-quality care at the time of the appointment or within 30 days of the appointment (see Table 1). The items below will be added together to form a score and the number of items completed out of the total will be the primary outcome measure compared across groups. We will measure these data for all patients with SLE, osteoarthritis, and inflammatory arthritis including RA seen by the provider during the 6-month study period as well as do a separate subgroup analysis focused on the patients who had their appointments audiorecorded. We will use electronic medical record data obtained from chart review, from RPDR and from the Enterprise Data Warehouse (EDW) to obtain these metrics.

Table 1. Quality metrics for diseases of interest		
Systemic lupus erythematosus (SLE)	**Rheumatoid Arthritis (RA)**	**Osteoarthritis**
Hydroxychloroquine (HCQ) initiation If lupus nephritis, immunosuppressive initiation, ACE-I or ARB, glucocorticoids Glucocorticoid prophylaxis (e.g. PPI, calcium/vitamin D, PJP if high dose) Contraception if on teratogenic medication Vaccinations Baseline HCQ eye exam and monitoring labs	DMARD initiation, or bDMARD initiation Folic acid if receiving methotrexate Glucocorticoid prophylaxis Contraception if on teratogenic medication Baseline X-rays, TB and hepatitis screening Labs within 1 month of methotrexate initiation Documentation of disease activity measure Vaccinations	Annual functional status assessment Baseline exams Annual pain assessment Recommendation for assistive devices

Secondary outcomes:
1) Change in provider IAT scores pre and post intervention. Dr. Hagiwara at VCU will participate in this. She will submit to VCU for IRB approval for participation using completely deidentified data. A Data Use Agreement is in process between the two institutions.
2) Differences in perception of patient centeredness, patient satisfaction, patient trust in the medical profession, experiences of discrimination and adherence (at time of visit and at 3 months) comparing the intervention to non-intervention group. This secondary outcome is only for that patients enrolled in the study (not the chart review-only non-interaction group). We will additionally measure adherence for a full 6 month period using the proportion of days covered measure now available through the EMR both for participants in the survey component and for the chart review patients.
3) Healthcare utilization – we will compare ED visits, hospitalizations, outpatient visits completed and outpatient visit no shows between the two arms in the 6 months following the encounter of interest. We will include chart review patients (non-interaction) as well as patients who consented and had audiorecorded encounters in this part.
4) Provider communication (measured only for patients enrolled in the study who had their appointment audiorecorded). Provider communication will be measured using the recorded transcripts and compared between arms: a) physician-to-patient talk time ratio, b) physician word use (number of first person pronouns, and number of positive and negative emotion-related words, divided by all words in the interaction) and c) total length of interaction. This part of the study will be led by Dr. Hagiwara (VCU). Dr. Hagiwara will have a Data Use Agreement to receive de-identified transcripts for this analysis and separate IRB approval through her institution to work with these deidentified qualitative data.

6. Data sharing
De-identified provider IAT data and de-identified transcripts of the patient-provider encounters will be sent via the MGB secure file transfer system to Dr. Hagiwara at VCU. She will have her own IRB approval to analyze these data and a Data Use Agreement is in process.

7. Risks and Discomforts

Providers may feel uncomfortable learning about the possibility of exhibiting a bias or prejudice not consciously recognized. They may also feel uncomfortable having patient-provider encounters audiotaped. However, the implicit bias literature demonstrates that real-time records (either audio or video) are superior to post-interaction interviews with patients and physicians because self-reports of behavior are often biased and incorrect. Both audio and video recording have been done extensively before and the acceptability of both has been demonstrated by a leading bias researcher (Penner et al. J Nonverbal Behav DOI 10.1007/s10919-007-0024-8, 2007). In this study 85% of patients approached were willing to be videotaped as well. In our study, we are minimizing risk by audiorecording only and not videotaping and all analyses will be conducted using de-identified transcripts. Similarly, patients will be linked with providers using unique identifiers and providers will be deidentified that way too. If providers feel uncomfortable with the aggregate results of the implicit bias association tests, they will have the opportunity to meet with the research team and be linked to resources and trainings through Harvard and MGB to help address these. Patients may also feel uncomfortable answering the survey questions. The informed consent outlines that their responses will not be seen by their treating rheumatologist and all findings will be deidentified before analysis. The study PI will be available to participants to discuss any concerns that arise.

Given the minimal risk nature of the study where providers are being encouraged to get to know their patients using this individuation intervention to provide high quality care regardless of race/ethnicity and socioeconomic status to better manage lupus, osteoarthritis, and inflammatory arthritis including RA, we do not anticipate any serious adverse events or adverse events. Provider data will be analyzed in aggregate and will be deidentified. After extensive discussion with multiple stakeholders, our NIA-appointed Safety Officer and MGB leaders, we have slightly modified our study procedures. In specific, if we find evidence of bias or discrimination, we will work with the MGB teams (Dr Sequist, Carla Carten, Jaarod Chin), who we have met with about this study, to determine the best BWH and MGH division-wide programs/trainings to help meet the needs we uncover. The content of these programs and trainings will be directly based upon specific provider biases that we detect. We also discussed this via email exchange with the Office of General Counsel, as well as the revised plan for deidentified data and follow-up through Carla Carten's office. If a deidentified, audiorecorded encounter transcript reveals explicit racism and harm to a patient, we will present this to the aforementioned teams and to the IRB in a deidentified manner to determine the most appropriate response.

The study will involve provider and patient-subjects. We believe that the risks to participation is no more than minimal risk. The primary risk to patients will be privacy of health information. We will minimize this risk as follows: all clinical encounter recordings and de-identified transcripts will be securely stored on a secure shared drive just for this project only accessible by essential study team members or on MGB secure Dropbox also only accessible by essential team members. The audiorecorders will be kept in a locked cabinet in the PI (Feldman) or Co-Is (Schoenfeld, Todd)'s locked offices. These offices are also within a locked central office, in a locked building with 24 hour security guards. To protect against the risk of inappropriate

disclosure of personal health information, the investigators will only receive data with encrypted identifiers. As described, all members of the research team have completed or will complete appropriate human subjects research training and patient privacy training related to the Health Insurance Portability and Accountability Act (HIPAA).

In the pilot trial, we do not anticipate the occurrence of any incremental adverse events as a result of providers receiving training about implicit bias, or for the individuation intervention to improve care for patients with lupus, osteoarthritis, or RA. Providers have ultimate oversight and continue to make all of the care decisions, but those in the intervention arm may elicit additional information to help guide their care and overcome their biases. The study team will not be providing any direct care to patients, and all treatment decisions will ultimately be made by the patients' medical teams at MGB. Any adverse events will be handled in the course of regular clinical care. We will also request a HIPAA waiver of patient authorization to access the her data necessary for outcome evaluation for individuals not participating in the provider-patient recording and survey component, and who did not decline participation in the recording/survey part.

Data for the study will be safeguarded by state-of-the-art security protocols. The facilities have 24-hour security and are protected by locked entrances. MGB has computer networks in place that employ up to date virus protection software and enable password protected access only to study investigators. The setup for analysis of these data will be the same as all the other IRB applications that our MGB research division submits for secondary use of data. In fact, we have an umbrella-approval place in place with the MGB IRB for using these types of HIPAA-limited data. All the datasets, including limited protected health information (PHI), will be stored only on secure servers at MGB's data center and will only be accessed by a limited number of individuals in the study team from this division who are all trained in data security and patient privacy. To ensure the confidentiality and security of all data, the research team operates a secure, state-of-the-art computing facility housed at MGB's data center. The MGB data center is a secure facility that houses both computing environments as well as clinical systems and electronic medical records for several large hospitals in Eastern Massachusetts. Entry into the computer room requires staffed computer room security. The Division's computers are connected to the MGB networking backbone with 10 gigabit-per-second fiber links. Network security is overseen by electronic medical records systems to the research team's data. All data are transmitted to programmers' workstations in an encrypted state. Backups are created using 256-bit AES encryption, the current Department of Defense standard for data security, and are stored in a locked facility. The redundancy, extensive data power, and security of our computer facility confirm our capacity to collect and manage data and ensure confidentiality for all project participants.

8. Benefits

There is no direct benefit to individuals who chose to participate in this study. The potential benefits to study participants include improved care quality in the intervention arm if the individuation intervention proves beneficial. In addition, providers will have the opportunity to participate in educational sessions to help reduce unconscious bias, which may improve the care they provide to their patients. Additionally, society may benefit in the future from both increased care quality, reduced influence of bias on clinical decision-making, and the accumulated knowledge that originates from this research. Based on the information learned from this pilot study, the researchers aim to develop curriculum and design a larger multisite intervention to more broadly understand the impact of these biases on care and to help providers use tools to address them.

9. Statistical Analysis

Power calculations are based on Aim 1's primary outcome (quality metric score). We account for an intracluster correlation coefficient (ICC) of 0.02 among patients of the same provider and assume a two-sided alpha level of 0.05. With 10 providers in each arm (N=20) and 8 patients per provider (N=160), we would have 84% power to detect a mean difference between arms of 0.5SD. If the ICC is 0.05, we would have 84% power to detect the same mean difference if 10 patients per provider were included.

All analyses will follow intention-to-treat (ITT) principles. All analyses will follow intention-to-treat (ITT) principles. For Aim 1, unadjusted and adjusted linear generalized estimating equation (GEE) models that account for patient clustering by providers will be used, with the quality metric score as the primary dependent variable, intervention arm as the primary predictor variable and covariates including hospital, and other factors that are either strongly correlated with the dependent variable (e.g. rheumatic disease) or imbalanced between the arms. We will use Millisecond software to program the IATs and calculate D scores that reflect response times and compare these findings across the two groups. For Aim 2, unadjusted and adjusted linear GEE models will be constructed with a) communication metrics and b) models for each survey score as the dependent variables, intervention arm as the primary predictor variable, and covariates as above. We will also analyze the transcripts qualitatively using Dedoose software and use the constant comparison method to evaluate and refine our themes and our codes.

10. Monitoring and Quality Assurance

Oversight:
Oversight of the pilot will be the responsibility of the pilot lead, Dr. Candace Feldman.
The pilot lead and study investigators will meet on a regular basis throughout the study period and will be in direct contact with practice managers and clinical leadership involved in the project to obtain ongoing feedback. In addition, the protocol will undergo IRB evaluation.

De-identified study data will be accessible at all times for the pilot lead and coinvestigators to review, if applicable. We will also ensure that all protocol deviations for the pilot study are reported to the NIH and the IRB according to the applicable regulatory requirements. Compliance of regulatory documents and study data accuracy and completeness will be maintained through an internal study team quality assurance process.

Determination:
Given the minimal risk nature of the study where providers are being encouraged to get to know their patients to provide high quality care regardless of race/ethnicity and socioeconomic status to better manage systematic lupus erythematosus (SLE), osteoarthritis, and inflammatory arthritis including rheumatoid arthritis (RA), we do not anticipate any SAEs or AEs.

Reporting:
As previously described, no SAEs or AEs are expected as part of this study, as the study team will not be providing any direct care to patients and all treatment decisions will ultimately be made by the patients' medical teams at MGB. However, we anticipate that the study team will be informed of any AEs or SAEs that do occur.
If we become aware of any AEs or SAEs throughout the course of the study, we will collect this information. Any reports of deaths will be submitted to the NIA Program Officer and to the Safety Officer (SO) within 24 hours. Any unexpected SAEs will be reported to the NIA PO, SO and the IRB within 48 hours of the study's knowledge of the SAE. All other reported SAEs and AEs received by the study team will be reported to the NIA Program Officer and to the SO quarterly. The Principal Investigator will follow IRB policy that any Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) and/or unanticipated adverse events will be reported to the IRB within 5 working days / 7 calendar days of the date the investigator first becomes aware of the problem. The Principal Investigator will also be maintaining an Adverse Event Log for the duration of the study.

General oversight of this project by the Brigham and Women's Hospital (BWH) pilot lead (Dr. Feldman) will occur throughout the study period, including regular contact with MGB clinical leadership involved in the project to obtain ongoing feedback. In addition, this protocol will undergo IRB evaluation.

This study will include safety monitoring from an independent safety officer (SO) to perform data and safety monitoring activities. This SO will advise NIA Program staff and the PI regarding participant safety, study risks and benefits, scientific integrity, participant recruitment, and ethical conduct of the study. Therefore, the pilot lead will appoint a designed individual with relevant study and disease-specific expertise to serve as SO, submitted to the NIA PO for approval. Following approval, the SO will receive a manual of operating procedures containing the study protocol and DSMP prior to study enrollment. Dr. Feldman has nominated Dr. Irene Blanco as the independent Safety Officer (SO), pending approval by the NIA PO, to act in an advisory capacity to the NIA PO and to evaluate the progress of the study.

Frequency of Data and Safety Monitoring:

De-identified study data will be accessible at all times for the pilot lead (Dr. Feldman) and co-investigators to review, if applicable. We will also ensure that all protocol deviations for the trials are reported to the NIH and the IRB according to the applicable regulatory requirements. Dr. Feldman will also be in routine contact with other MGB clinical leadership to obtain any feedback from clinicians or patients regarding the study. Compliance of regulatory documents and study data accuracy and completeness will be maintained through an internal study team quality assurance process. Safety reports are sent to the SO at least biannually and will include a detailed analysis of study progress, data and safety issues.

Data Analysis and Coordination
Designated individuals at BWH will collect and process all data related to the study.

Content of Data and Safety Monitoring Report
Study data including patient study status, participant descriptive information, and safety information, will be made available to the pilot lead and study investigators. Given the minimal risks involved in participation, we do not anticipate any unacceptable adverse events.

DSMB Membership and Affiliation
Given the minimal risk of this single-site study conducted within a non-vulnerable population, DSMB oversight is not required for this trial.
The following individual has accepted the position as Safety Officer (SO). The SO will be reviewed and approved by the NIA. Should there be any questions regarding the independent of the SO, it will be addressed and corrected if necessary, at that time.
Irene Blanco, MD, MS
Prof. of Medicine, Division of Rheumatology, Associate Dean for Office of Diversity Enhancement, Albert Einstein College of Medicine
The SO nominated for this study is Dr. Irene Blanco, MD, MS. Dr. Blanco is a Professor in the Department of Medicine at Albert Einstein College of Medicine. She is also the Associate Dean for Office of Diversity Enhancement. As a researcher, she studies social determinants of health and health disparities in rheumatology. She is also a leader in graduate and professional medical education curriculum around implicit bias and health disparities. Her experience both as a researcher and as an educator in health disparities make her qualified to serve as an SO for this specific project.

Conflict of Interest for DSMB/SO
The appointed Safety Officer has no direct involvement with the study or conflict of interest with the investigators or institutions conducting the study. The SO will sign a Conflict of Interest Statement which includes current affiliations, if any, with pharmaceutical and biotechnology companies (e.g., stockholder, consultant), and any other relationship that could be perceived as a conflict of interest related to the study and / or associated with commercial interests pertinent to study objectives.

The Safety Officer (SO) will conduct data and safety monitoring activities for this project. The SO will act in an advisory capacity to the NIA PO and to evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome. The SO will make recommendations to the Program DSMB and NIA PO concerning the continuation, modification, or conclusion of the trial.
The study team will prepare safety reports at least biannually to be reviewed by the SO, Program DSMB and NIA for recommendations for or against the trial's continuation, as well as

any modification to the study. In addition to safety data, the SO will consider recruitment and retention rates and whether delated recruitment raises concerns of futility and ethical considerations.
Specific SO responsibilities include:
• Review the entire IRB-approved study protocol and the MOP, with regard to participant safety, recruitment, randomization, intervention, data management, quality control and analysis and the informed consent document.
• Recommend changes to the protocol and the informed consent form, when applicable.
• Identify the relevant data parameters and the format of the information to be regularly reported.
• Recommend participant recruitment be initiated after receipt of a satisfactory protocol. If the need for modifications to the protocol, the MOP, consent form, DSMP or any other study document is indicated by the NIA PO, the SO will postpone its recommendation for the initiation of participant recruitment until after the receipt of a satisfactory revised protocol(s) or other study documents.
• Review masked and unmasked data. These data can be related to safety, recruitment, randomization, retention, protocol adherence, trial operations, data completeness, form completion, intervention effects, gender and minority inclusion.
• Identify needs for additional data relevant to safety issues and request these data from the study investigators.
• Propose additional analyses and periodically review developing data on safety and endpoints.
• Consider the rationale for continuation of the study, with respect to progress of randomization, retention, protocol adherence, data management, safety issues, and outcome data (if relevant) and make a recommendation for or against the trial's continuation.
• Review and make recommendations on proposed protocol changes, and/or new protocols proposed during the trial and make recommendations to NIA on whether to approve the requests.
• Provide advice on issues regarding data discrepancies found by the data auditing system or other sources.
• Review manuscripts of trial results if requested by the NIA PO who may seek SO review of manuscripts reporting major outcomes prior to their submission for publication.

11. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☒ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)

- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☐ Additional privacy and/or confidentiality protections

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APPENDIX A

There is no DSMB for this project. There is a Safety Officer as described below.

Safety Officer

A Safety Officer (SO) will be convened for safety monitoring of this research study per determination of the National Institutes of Health. The following characteristics describe the SO for this study (Check all that apply):

☒ The Safety Officer is independent from the study team and study sponsor.

☒ A process has been implemented to ensure absence of conflicts of interest by the SO.

☒ The SO has the authority to intervene on study progress in the event of safety concerns, e.g., to suspend or terminate a study if new safety concerns have been identified or need to be investigated.

☒ Describe number and types of (i.e., qualifications of) members:
Name: Irene Blanco, MD
Title, Organization: Professor of Medicine, Albert Einstein College of Medicine
Dr. Blanco is a leader in health disparities initiatives, provider education and DEI efforts at her institution and nationally. She was spoken widely about implicit bias awareness and provider based interventions as a way to reduce disparities in rheumatic disease outcomes.

☒ Describe planned frequency of meetings:
Per the NIA Notice of Award, recruitment is restricted until the SO has reviewed and recommended approval to NIA, with NIA's concurrence, the DSMP, IRB-approved study protocol, consent documents, and Manual of Operating Procedures.

Per the Data Safety Monitoring Plan, safety reports are sent to the SO at least twice a year and will include a detailed analysis of study progress, data and safety issues.

☒ SO reports with no findings (i.e., "continue without modifications") will be submitted to the IRB at the time of Continuing Review.

☒ SO reports with findings/modifications required will be submitted promptly (within 5 business days/7 calendar days of becoming aware) to the IRB as an Other Event.