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Howard University
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Title: Howard University (HU) Rheumatoid Arthritis (RA) Early Diagnosis Clinic (HU-RAEDC). Grant ID# 26216577. Mercedes Quiñones, MD; Sharon Dowell, MD; Arielle McDonald MPH; Gail Kerr, MD.

Abstract: Expedient assessment (≤ 12 weeks) of patients suspected of having RA is beneficial as early diagnosis and management of RA confers a greater likelihood of achieving remission and less joint destruction. The goal of this project is to provide primary care practitioners (PCPs) with a rapid referral system to rheumatology specialists, thus facilitating early diagnosis and treatment of RA. The primary target population is the underserved ethnic minority community of the greater Washington DC area and the PCPs who serve this population. We believe both groups will directly benefit from our intervention. In order to evaluate the success of our project, we will evaluate the following outcomes: length of time between the PCP referral and rheumatology clinic visit, number of patients referred that have an RA diagnosis, number of patients initiated on DMARD therapy within 12 weeks of referral, difference in RA disease activity measures between patients diagnosed early (≤ 12weeks) vs. those accessing the routine referral system, and PCP satisfaction of utility and access to the referral system.

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Reviewer Comments:

ERPM#1: Will the team schedule time for providers to review the tele-consults or will they do it "after hours?" Concerned about time burden on rheumatologists reviewing the consults with scores 6. The HU rheumatology team will review all of the RA diagnosis forms received from the PCPs (see Appendix A) once weekly on an already scheduled day in the Division of Rheumatology. Forms that score ≥ 6 will be will be given a rheumatology appointment in the HU-RAEDC within 2 weeks. Forms that have incomplete information and/or PCP inquiries will be set-up for a 5-10 minute "tele-consultation" between the PCP and the rheumatologist for further discussion within 1 week. PCPs will also be given the option to submit the form via use of an electronic application which can be accessed on a smart device i.e. phone, tablet.

ERPM#2: It would be useful for the PCP to complete an educational module as an introduction to the program. My biggest concern is whether the PCP would find this too time-consuming to participate. The rheumatology team will be providing a direct, on-site introduction and teaching session to the PCPs at the main clinic with the largest number of referring providers. The form to be completed by the PCP is simple and comprised of 4 questions (see Appendix A) and can be submitted either via electronic application, fax, or secure e-mail. If needed, the duration of the direct "tele-consultation" will be limited to 5-10 minutes in order to avoid disruption of routine daily practice. "Tele-consultation" would also, over time, hone PCP clinical skills in detecting synovitis and differentiating inflammatory from non-inflammatory arthritides.

ERPM#3: Not clear how data will be collected to evaluate the project. Ease of use and satisfaction data collected but how will changes in time of referral from PCP be measured? How will PCPs be made aware of the expedited referral process? What kind of training is necessary for PCPs? Important access to specialist based on what is on a form; forms are not always completed correctly. Changes in time of referral from PCP will be measured by documenting the time interval between date of referral form and initial rheumatology appointment in those patients referred through the HU-RAEDC vs. those referred by conventional methods. The "tele-consultation" between the PCP and rheumatologist will address incomplete data on RA diagnosis forms and/or any PCP inquiries. (See responses to ERPM#2 and ERPM#3).

ERPM#4: I am not sure about it decreasing provider burden as the PCP will need to order the tests need to score the criteria and the rheumatologists is going to have to review a significant amount of data through the triage process. The RA diagnosis form is a one-page data sheet (see Appendix A). Ordering RA-related laboratory assays prior to a rheumatology appointment is seminal in improving the time to diagnosis. Scoring of the RA diagnosis form is done by the Rheumatologist, not the PCP, and will take < 5 minutes. Furthermore, if the form is submitted via electronic application, it will be scored automatically.

ERPM#5: Needs assessment data needs to be more specific to the institution and patient population. The outcomes evaluation includes the metrics to be assessed but no level of expected change (goes back to lack of needs assessment data) and more specifics on how these metrics will be collected. The average wait time for an initial rheumatology consultation at HU is 3 months. Although there are a number of academic and non-academic rheumatology practices in close proximity to HU, many of them do not accept the insurance plans that are typically used by our ethnic minority, low SES, and underserved patient population. Further, these other academic practices that do accept these insurance plans have longer wait times for appointments, exceeding 4 months. As ethnic minorities and low SES individuals have worse outcomes for RA, there is the need – and the aim of this project - to decrease wait times for first visits, diagnosis of RA, and initiation of RA therapies. Therefore, with this project, it is expected that there will be a > 50% decrease in time to rheumatology appointments for those patients referred through the HU-RAEDC. Outcome evaluation data with regards to disease activity i.e. CDAI, RAPID-3 will be collected at baseline and at each patient visit, with expected changes reflective of a "meaningful clinical response" i.e. Δ - 6.5, Δ - 3.6 respectively.

ERPM#6: No comments and/or questions to respond to by ERPM#6.

ERPM#7: A full proposal should address how the increased PCP burden (to obtain labs and score disease activity) and rheumatologist burden (to evaluate data in triaging patients) will be accommodated in a busy clinic setting. See responses to ERPM#1 and #2 above.

ERPM#8: No comments and/or questions to respond to by ERPM#8.

Overall Goal & Objectives: To provide PCPs serving an ethnic minority population with a rapid referral system (RA diagnosis form; "tele-consultation") to rheumatology specialists, facilitating early diagnosis and treatment of RA.

In this proposal, we aim to facilitate the early diagnosis of RA in an underserved community via overcoming one of the recognized barriers to rheumatology specialty care: time from presentation to the PCP-to-the assessment by the rheumatologist. HU is the lead site of the Ethnic Minority Rheumatoid Arthritis Consortium (EMRAC), a registry of over 1600 patients with RA. The impact of late diagnosis and delayed treatment in RA is well-known, and HU is committed to improving care in ethnic minority and underserved populations by surmounting the existing barriers that limit standard-of-care in these patients.

1. Decrease time from referral by PCP to assessment by rheumatologist in cases of suspected RA to < 4 weeks.
2. Improve PCP diagnosis of RA as measured by increased number of patients with suspected RA that are actually diagnosed with RA after initiation of HU-RAEDC.
3. Compare disease activity and outcome measures (CDAI, RAPID-3) between RA patients of the HU-RAEDC and those of the general HU rheumatology clinic.
4. Measure PCP satisfaction of utility and access to the referral system.

Current Assessment of Need in Target Area: The average wait time for an initial rheumatology consultation at HU is 3 months. Although there are a number of academic and non-academic rheumatology practices in close proximity to HU, many of them do not accept the insurance plans that are typically used by our ethnic minority, low SES, and underserved patient population. Even at those local academic practices that do accept these insurance plans, the average wait time is even longer i.e. > 4 months. It is well-known that early assessment (≤12 weeks) of patients suspected of having RA is beneficial as early diagnosis and management of RA confers a greater likelihood of achieving remission and less joint destruction.[1] The positive 5-year clinical outcomes of an early ≤ 6 months RA cohort (ESPOIR cohort) was related to early specialty referral and, thus, early effective treatment.[2] However, only a minority (31%) of RA patients are in fact assessed within 12 weeks of symptom onset, and contributing factors include delayed patient presentation, failure of recognition of inflammatory arthritis by PCPs, and limited access to rheumatology consultation.[3] Furthermore, the underserved patient population in the greater Washington DC area faces additional challenges including overall limitation in access to healthcare, language barriers, and low SES. In a multi-site (including HU) ethnic minority cohort of RA patients (EMRAC), significant differences were found amongst ethnic groups across multiple domains including duration of disease.[4] African-American and Hispanic RA patients had longer disease duration compared to Caucasian patients, and less than

5% met inclusion criteria for randomized controlled clinical trials (RCTs), particularly clinical studies for early disease.[4,5] Thus, it is imperative to facilitate the early diagnosis of RA and improve its clinical outcomes in ethnic minority patients. In order to facilitate the early diagnosis of RA and improve outcomes in ethnic minorities, improved access to specialty care, and increased awareness of PCPs of the initial presentation of the disease and the sequelae of delayed diagnosis are paramount. The existing opportunities that provide these to the RA patient and the PCP are limited, particularly at the first encounter, requiring novel interventions - if the tenet of early diagnosis and treatment of RA are to be achieved.

Target Audience: The primary target population for this project is the underserved ethnic minority community of the greater Washington DC area and the local PCPs who serve this population. We believe both groups will directly benefit from the intervention. HU already has an established relationship with the Unity Health Care network of primary care clinics, and we hope to strengthen this relationship through this collaborative project. The model will be continuously reassessed, and if successful, expanded to a wider referral base. There is also potential for this triage design to be replicated by other local academic and non-academic rheumatology practices, as well as general applicability at a national level. Our project design can then serve as a template for other practices and institutions, as "tele-medicine" is becoming more feasible and popular across the US.

Project Design & Methods: The HU-RAEDC is a rapid referral system that will provide referring PCPs with access to an RA diagnosis form and direct "tele-consultation" with the HU rheumatology team for patients with suspected RA. PCPs will be provided with an HU-RAEDC referral RA diagnosis form (see Appendix A) that will be transmitted by electronic application for smart phone, fax, or secure email to the HU rheumatology team. The HU-RAEDC referral form incorporates American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) RA classification criteria.[6] In addition to history, physical examination, and laboratory data including Anti-citrullinated protein antibody (ACPA), Rheumatoid factor (RF), C-reactive protein (CRP), & Erythrocyte sedimentation rate (ESR), patients will be assigned a score based on RA classification criteria.[6] The HU-RAEDC referral form is simple and comprised of only 4 questions in order to make the entire process by the PCP as easy as possible; taking no more than 5 minutes to complete, and further expedited if it is transmitted via electronic application. PCPs will also submit pictures of the patient's hands (and/or other affected joints), if relevant, by electronic application or secure email to the HU rheumatology team. The HU rheumatology team, primarily the rheumatologist and rheumatology staff on-call, will review all of the HU-RAEDC referral forms received once weekly on a preassigned day. Patient forms receiving a score of ≥ 6 will be seen in the HU-RAEDC clinic by a rheumatologist within 2 weeks. Two appointment slots will be reserved per week in the general HU rheumatology clinic, serviced by 3 rheumatologists, and will be designated as a "virtual" HU-RAEDC clinic to accommodate the HU-RAEDC referrals. The number of available appointments will be reassessed monthly, and revised based on demand in order to maintain timelines for appointments. Patients with scores of < 6 will be assigned appointments in the general HU rheumatology clinic. Referral forms with incomplete/missing data and/or PCP inquiries will prompt a direct "tele-consultation" between

the PCP and the rheumatologist within 1 week of receipt. Any additional details of the clinical case and missing data will be obtained and discussed at this time. The duration of the direct "tele-consultation" will be limited to 5-10 minutes in order to make the entire process as short and simple for the referring PCP as possible. After this one-on-one encounter, those patients identified as having a high suspicion for RA will be given an appointment in the HU-RAEDC within 2 weeks. Frequency of patient follow-up visits will be determined by the treating rheumatologist. The HU-RAEDC project targets underserved ethnic minority patients with multiple barriers to rapid access to both primary and specialty medical care, and will facilitate one-on-one interaction between the referring PCP and the rheumatologist. Although other strategies for early identification of inflammatory arthritis have been proposed, none have utilized a one-on-one interaction approach or targeted a specific disease or population subset.[3,7] In this protocol, we are building upon an already established relationship between HU rheumatology and a local network of primary care clinics, providing one-on-one teaching in the early detection of inflammatory arthritis, while instituting a mechanism to diagnose and treat early RA.

Evaluation Design:

1. Assessment of time from PCP referral to rheumatology assessment in patients with suspected RA. [Aim: Decrease time to initial rheumatology appointment by 50%]
2. Assessment of percentage of new RA diagnoses after initiation of the HU-RAEDC. [Aim: Increase in "true" vs. "false" diagnoses of RA over a 12-month period (measure of learning, performance, and competence of referring PCP)]
3. Measurement of disease activity and outcome measures i.e. CDAI, RAPID-3 in patients diagnosed with RA early and started on DMARD therapy within 12 weeks of referral. [Aim: Decrease CDAI, RAPID-3 scores by - 6.5, - 3.6 respectively]
4. Assessment of number of patients with RA diagnosis whom are started on DMARD therapy within 12 weeks of referral. [Aim: Increase number of patients whom are started on DMARD therapy within 12 weeks of referral]
5. Assessment of satisfaction of utility and access to the rheumatology rapid referral system by referring PCPs via questionnaires. [Aim: Increase ease of PCP referral to rheumatology clinic without increasing PCP burden/workload (measure of satisfaction)]

Changes in time of referral from PCP will be measured by documenting the time interval between date of HU-RAEDC referral form and initial rheumatology appointment in those patients referred through the HU-RAEDC vs. time interval between date of generic PCP referral and initial rheumatology appointment in those patients referred through conventional methods. Outcome evaluation data with regards to time to initial rheumatology visit will be expected to decrease by 50% in the HU-RAEDC group. Outcome evaluation data of RA disease activity i.e. CDAI, RAPID-3 will be collected at baseline and at each patient visit, and "meaningful clinical response" will be defined as follows: a Δ - 6.5 & Δ - 3.6, respectively. The questionnaires from the referring PCPs will assess (a) ease of use of the HU-RAEDC system, (b) comfort level with initial management of the patient suspected of having RA, and (c) improved knowledge of diagnosis and management of RA patients (see Appendix B). We expect that the

implementation of the HU-RAEDC will result in *improved* time to diagnosis and treatment as well as *improved* disease outcomes.

Detailed Workplan & Deliverables Schedule: Proposed start date-to- end date for project: July 2016 - May 2018. The proposed timeline will allow advertisement and adoption of the HU-RAEDC, "tele-consultations," patient consultations, and patient follow-up over a 12-month period. The "lead-in" phase during which the HU rheumatology team will make on-site visits to the local network of PCP clinics will be 6-8 weeks. The "recruitment" phase during which the HU-RAEDC will be implemented i.e. HU-RAEDC referral forms reviewed/scored and patients given expedited rheumatology appointments will be 6 months. The "assessment" phase during which the HU-RAEDC intervention patients confirmed to have an RA diagnosis are seen for routine rheumatology visits will be 1 year. The "post-intervention" phase during which evaluation outcome data will be collected/analyzed will be 3 months.

Deliverables	**Schedule/Timeline**
"Lead-in" Phase	July 2016 - August 2016
"Recruitment" Phase	September 2016 – January 2017
"Assessment" Phase	February 2017 – February 2018
"Post-intervention" Phase	March 2018 – May 2018
CDAI, RAPID-3	Baseline; Each patient consultation
PCP questionnaires	February 2017 – April 2017; March 2018 – April 2018

Appendix A ("HU-RAEDC referral form"):

PCP _____

Date _____

Patient DOB _____

Patient initials _____

Section #1: JOINT INVOLVEMENT

Number of "small" joints involved _____

Number of "large" joints involved _____

(Definition of "small" joints: hands [metacarpophalangeal joints; proximal interphalangeal joints including thumb interphalangeal joints], wrists, feet [2nd-5th metatarsophalangeal joints]; Definition of "large" joints: shoulders, elbows, hips, knees, & ankles)

Section #2: SEROLOGIES

ACPA (value) _____

RF (value) _____

Section #3: ACUTE PHASE REACTANTS

CRP (abnormal *or* normal) _____

ESR (abnormal *or* normal) _____

Section #4: DURATION OF SYMPTOMS

< 6 weeks _____

≥ 6 weeks _____

(Please check one)

Appendix B ("PCP Assessment Questionnaire")

PCP _____

Date _____

(Please circle one)

1. I think the HU-RAEDC referral system is easy to use.

Disagree Somewhat Agree Strongly Agree

1 2 3 4 5 6 7 8 9 10

2. I think the HU-RAEDC referral system is too time-consuming.

Disagree Somewhat Agree Strongly Agree

1 2 3 4 5 6 7 8 9 10

3. I think the HU-RAEDC referral system improved my patients' outcomes.

Disagree Somewhat Agree Strongly Agree

1 2 3 4 5 6 7 8 9 10

4. Overall, I am comfortable with differentiating between patients that have inflammatory arthritis i.e. RA vs. non-inflammatory arthritis.

Disagree Somewhat Agree Strongly Agree

1 2 3 4 5 6 7 8 9 10

References:

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