

Leveraging Health Information Technology and Team Change to Improve Cardiovascular Disease Prevention in Rheumatoid Arthritis

Abstract

This project will test a practical multi-faceted system-based intervention that aims to: increase cardiovascular disease (CVD) risk factor assessment among rheumatoid arthritis (RA) patients; systematically identify unaddressed increased CVD risk or uncontrolled risk factors; increase rheumatologist counseling about CVD risk; and increase appropriate pharmacotherapy for CVD risk reduction (specifically moderate-to-high intensity statins and antihypertensive drug treatment) by promoting co-management and improving physician-to-physician communication. The study will be performed in a diverse group of over 1200 rheumatoid arthritis patients from a large group practice. We will attempt to address barriers on multiple fronts. There are four main intervention components. (1) Provider education: We will develop learning sessions that emphasize the CVD risk in RA along with specific clinical recommendations. (2) Point-of-care clinical decision support directed at rheumatologists: we will use functionality in the electronic health record (EHR) to deliver preventive-cardiology-related decision support to rheumatologists. (3) Provider feedback: we will provide monthly email and quarterly in-person feedback to rheumatologists about how well their RA patients met preventive cardiology care metrics. (4) Care management: on a rolling basis, a non-clinician care manager will use a query of EHR data to determine RA patients with upcoming rheumatology appointments and will send patients who have addressable preventive cardiology needs individualized CVD risk messages. We will measure outcomes using EHR data obtained from a data warehouse and will interview participating rheumatologists. Because this intervention will be done system-wide, we will use interrupted time-series modeling to determine if the intervention improved outcomes more than underlying temporal trends.

Overall Goal & Objectives

The overall goals of this project are to implement and test a practical multi-faceted system-based intervention that will: (1) increase CVD risk factor assessment (blood pressure, total and HDL cholesterol, diabetes mellitus [DM] status, and smoking status) among RA patients; (2) systematically identify unaddressed increased CVD risk or uncontrolled risk factors in a manner that is both consistent with current U.S. guidelines and also accounts for the increased CVD risk in RA; (3) increase rheumatologist counseling about CVD risk; and (4) increase appropriate pharmacotherapy for CVD risk reduction (specifically moderate-to-high intensity statins and antihypertensive drug treatment) by promoting co-management and improving physician-to-physician communication. We will accomplish these goals using provider education, provider-facing computerized clinical decision support, electronic health record (EHR)-supported quality measurement and provider feedback, and rheumatology care-team redesign using a care manager.

This project aligns directly with the focus of the RFP in that it will implement and test feasible strategies intended to accelerate the adoption of evidence-based practices to address modifiable CVD risk factors and reduce the burden of CVD in RA patients.

Objectives: Our primary measurable objectives are to (1) increase to 75% the proportion of eligible RA patients with all major CVD risk factors assessed, (2) increase to 55% the proportion of patients with a 10-year CVD risk of at least 5% (based on risk factors or established CVD) who are prescribed a moderate or high intensity statin, (3) achieve LDL (or non-HDL) cholesterol reduction of ≥ 30 mg/dL for at least 20% of RA patients previously untreated with statins who have a 10-year CVD risk of at least 5%, (5) increase the rate of appropriate hypertension diagnosis among RA patients with persistently elevated blood pressure.

Technical Approach

Current Assessment of Need Nationally and in the Target Population

Cardiovascular disease is the leading cause of death in individuals with RA. Patients with RA are at 1.5-2.0-fold increased risk of CVD morbidity relative to the general population.[1-4] In a meta-analysis of 24 studies, the risk of coronary heart disease mortality was increased 1.59 fold and the risk of cerebrovascular mortality was increase 1.52 fold in individuals with RA compared to the general population.[1] Many RA patients have modifiable CVD risk factors.[5] Despite the high burden of CVD and recommendations by the European League Against Rheumatism (EULAR) for routine cardiovascular risk assessment and management, it was recently shown that both rheumatologists and primary care physicians identify and manage cardiovascular risk factors less often in RA patients compared with controls from the general population. [2, 6-8]

Table 1. Atherosclerotic Cardiovascular (ASCVD) Risk Factors and Treatment among Study Site RA Patients*

Characteristic	Entire cohort N = 1249	Known CVD N = 113	ASCVD risk ≥5% N = 220	Risk < 5%, with diabetes or LDL ≥ 190 N = 29	Other N = 887
Age, mean, y	57.1	67.6	68.5	56.7	52.9
Female, %	83.6	73.5	74.5	93.1	87.0
Race, %					
African Am	16.3	24.8	30.0	17.2	11.8
White	52.8	57.5	47.3	27.6	54.5
Asian	2.5	2.7	3.2	6.9	2.1
Other/missing	28.5	15.1	18.6	48.3	22.7
Hispanic/Latino, %	11.3	12.4	9.1	24.1	11.3
Current smoking, %	5.4	8.0	10.0	0	4.2
Drug treated HTN,%	1.4	5.3	5.7	3.0	0.6
Uncontrolled BP,%	14.3	23.9	25.5	24.1	10.0
Diagnosed diabetes, %	7.4	21.2	15.9	89.7	0.8
Anti-thrombotic drug use, %	23.3	80.5	29.1	17.2	13.6
Statin use, none,%	73.7	20.4	61.0	48.3	84.5
Low potency	6.2	14.2	12.3	6.9	3.7
Mid potency	15.4	41.6	22.2	41.4	9.5
High potency	4.6	23.9	4.5	3.4	2.3
Unmeasured cholesterol, %	49.3	17.7	0	0	65.2
Unmeasured glucose/A1c, %	7.1	0.9	1.8	10.3	9.1

*Bolded numbers indicate populations with primary targets for clinical intervention

Unmeasured and Uncontrolled CVD Risk Factors are Prevalent in our Target Area

Inadequate CVD risk factor screening and treatment is prevalent in the population of RA patients served by the Northwestern Medical Faculty Foundation (NMFF). We performed queries of our Enterprise-wide Data Warehouse (EDW) using Structured Query Language and identify RA patients with 2 or more rheumatology office visits in the preceding 18 months and 2 or more rheumatology visits with ICD9-CM diagnosis codes for rheumatoid arthritis. We assessed whether patients had established CVD, and collected data for cholesterol, blood pressure, antihypertensive and lipid lowering medication therapy, and smoking and DM status as we have done in our prior work conducted among non-RA populations.[9, 10] We calculated atherosclerotic CVD risk (the risk of symptomatic coronary or cerebrovascular disease) using equations from the 2013 ACC/AHA risk assessment guideline and identified patients whose 10-year estimated risk exceeded 5%.[11] We chose CVD risk of ≥ 5% because at this level the

ACC/AHA guideline recommends statin therapy be considered, and strongly recommends it at a level of $\geq 7.5\%$. [12] RA patients with CVD risk estimated at 5% likely have a true level of risk exceeding 7.5% because CVD risk is increased approximately 1.5 fold in RA. [1, 7] As depicted in Table 1, among a diverse group of 1249 RA patients cared for in the NMFF group practice, **only half had all major risk factors assessed** (data missing for lipids [49%] and DM [7%]). Among those potentially eligible for a statin (known CVD or 10-year CVD risk of $\geq 5\%$), **only 40% of potentially eligible RA patients were treated with a moderate or high intensity statin and nearly half were prescribed no statin**. Most recent blood pressure was $<140/90$ for 86% of the cohort. Diabetes and current smoking prevalence were low (7.4% and 5.4% respectively). Therefore the largest unaddressed needs and major intervention targets in our clinical practice are promoting complete risk factor assessment and the appropriate use of statins. Addressing uncontrolled hypertension, newly discovered DM and smoking are secondary targets due to their low prevalence in our cohort.

Primary Target Audience for the Intervention

This includes primarily the group of rheumatologists from a large group practice. Secondly, we will target internists, and other primary care providers managing RA patients in our healthcare system. We anticipate direct benefit will accrue to RA patients who receive interventions to reduce CVD risk. In addition, other organizations will benefit from this demonstration of the effectiveness of a feasible, generalizable set of tools that can be used for population health management to optimize care on a system-wide basis.

Project Design and Methods

Background: There are multiple reasons for sub-optimal healthcare system performance. We perceive the following barriers to addressing CVD risk in RA. **Patient-level barriers:** Patients may be unaware of the increased CVD risk in RA, pay more attention to RA than other health risks, and if they are women, under-appreciate CVD which is often thought of as a man's disease. **Provider-level barriers:** RA patients may see generalist physicians infrequently, generalists may not appreciate the CVD risk in RA, or they may be concerned about drug-drug or drug-disease interactions that reduce their likelihood of prescribing medications to lower CVD risk. Rheumatologists have competing demands during visits (e.g. managing disease activity) or may not view CVD prevention as within their scope of work. Also, RA patients may have low LDL despite high CVD risk, and the opportunity to use a statin (which is predominantly risk-based, not LDL-based, in the current guideline [12]) may go unrecognized.

Overview of the Intervention: Our intervention addresses barriers on multiple fronts in order to achieve a meaningful improvement in CVD risk factors and increases in appropriate treatment. There are four main components. (1) Provider education: Didactic education is likely a necessary first step to increase awareness of the magnitude of CVD risk among RA patients and to generate a sense of accountability among providers. We will develop an interactive learning session that emphasizes the higher CVD risk in RA, recommends risk factor monitoring, and presents strategies that can be used to modify CVD risk. We will produce one version of the lecture for a generalist audience and one for a rheumatology audience. (2) Point-of-care clinical decision support directed at rheumatologists: we will use functionality in the Epic EHR to deliver

actionable preventive-cardiology-related computerized clinical decision support to rheumatologists at the point of care. (3) Provider feedback: on a monthly basis, we will provide email feedback to rheumatologists about how well their RA patients met preventive cardiology care metrics. Approximately quarterly, Dr. Majka and Dr. Ruderman will review the results of these performance measures with the rheumatology group during staff meetings. (4) Care management: on a rolling basis, the care manager/project coordinator will use a query of EHR data to determine RA patients with upcoming rheumatology appointments within the next month and will send patients who have addressable preventive cardiology needs individualized mailed (or patient portal) messages.

Provider Education

Didactic educational sessions: Didactic education is likely a necessary first step to increase awareness of the magnitude of CVD risk among RA patients and to generate a sense of accountability among providers. We will initially develop and deliver two interactive learning sessions, each to be delivered to both a generalist audience and a rheumatology audience. These educational sessions will be given at two Northwestern forums: 1) Rheumatology Grand Rounds, and 2) General Internal Medicine Noon Conference. The first will be a lecture provided by Dr. Majka which will describe the higher CVD risk in RA, outline recommendations for risk factor monitoring, and present strategies that can be used to modify CVD risk. This lecture will emphasize the currently described low rates of risk factor screening and modification among RA patients compared with non-RA patients. The second lecture will be delivered by Dr. Persell and will describe his and other's work using health information technology and care team change to improve cardiovascular risk factor assessment and management. These sessions will also serve to briefly describe our study and alert the providers to its upcoming start date.

Demonstration of point-of-care clinical decision support: At the roll out of the study, an interactive session will be provided at another Northwestern Rheumatology Grand Rounds in order to fully orient our target rheumatology audience to the study. This session will demonstrate decision support functionality (see additional details below). This will include: 1) the EHR "Best Practice Alerts" which will alert the rheumatologists to a patient's need for risk factor measurement or risk factor modification; 2) EHR order sets to facilitate risk factor measurement and printing of patient educational materials; 3) EHR letter templates to assist rheumatologists to communicate to the generalists relevant information about a patient's CVD risk factors and requests for management of risk factors; and 4) the role the care manager will play to facilitate risk factor assessment, communication with the patients and their generalists, and follow up on risk factor management. The care manager will be present to meet the rheumatologists. The EHR design specialist will be present for this live visual demonstration of the EHR tools using test patients in the actual EHR system projected for group viewing. In addition, snapshots of the EHR tool web pages will be provided as electronic and paper handouts for the rheumatologists to keep. These will be posted in the Rheumatology physician work areas as well.

Point-of-care clinical decision support directed at rheumatologists: We will implement multiple clinical decision support rules into the Epic electronic health record using standard functionality

called “Best Practice Alerts” which we will trigger for rheumatology providers when specific criteria are met (e.g. a risk factor is unmeasured, a risk factor is uncontrolled, or risk is sufficient to warrant consideration of statin treatment). We will tie these to order sets to facilitate risk

Table 2. Candidate Computerized Clinical Decision Support Rules for CVD Prevention in RA

Decision Support	Description (supporting guidelines)	Linked Functions
Consider checking lipids	Over age 40, not statin treated, no total and HDL cholesterol measured in past 5 years [7, 12]	Order set to order lipid panel (fasting) or total and HDL cholesterol (non-fasting)
Consider screening for diabetes	No glucose or HbA1c in past 3 years [7, 13]	Order set to order glucose (fasting) or HbA1c (non-fasting)
Consider moderate to high potency statin for primary prevention	Aged 40-75 years, ASCVD risk of $\geq 5\%$, not treated with a moderate or high potency statin [7, 12]	Letter template to primary care provider, written patient education, documentation of exceptions
Consider high potency statin for secondary prevention	Aged 40-75 years, diagnosed ASCVD, not treated with a high potency statin [7, 12]	Letter template to primary care provider, written patient education, documentation of exceptions
Consider addressing uncontrolled hypertension	Diagnosed hypertension, blood pressure $>140/90$ (or $>150/90$ and age ≥ 60)[14]	Letter template to primary care provider, written patient education, documentation of exceptions
Consider additional evaluation or treatment for undiagnosed hypertension	No hypertension diagnosis, mean blood pressure $>140/90$ (or $>150/90$ and age ≥ 60)[14]	Letter template to primary care provider, written patient education, documentation of exceptions
Consider counseling or referral for smoking cessation	Current smokers [7] [15]	Letter template to primary care provider, written patient education, documentation of exceptions
Antiplatelet drug for secondary prevention	Diagnosed ASCVD and no antithrombotic drug prescribed[16]	Order set for aspirin ordering, letter template to primary care provider, written patient education, documentation of exceptions

factor measurement, and provision of printed patient education materials. We will build letter templates to assist rheumatologists in communicating relevant information about CVD

prevention in RA to the patients' generalist physicians, as well as specific requests for medical management of risk factors. We have extensive experience designing and implementing these kinds of tools.[17, 18] Table 2 provides a list of candidate decision support rules. We will calculate CVD risk using algorithms outside of Epic and use existing functionality to import these values into Epic. To facilitate communication between rheumatologists and primary care providers about CVD risk, need for risk factor management and potential concerns about drug-drug and drug-disease interactions, we will write letter templates and text for patient instructions that can be generated when a rheumatologist interacts with the clinical decision support, or used independently.

Provider feedback: We will use queries of EHR data to generate feedback reports to rheumatology providers. We will do this in a similar fashion to what we have done for our baseline measures (Table 1) to determine the proportion of individual rheumatologists' RA patients who have unassessed or uncontrolled risk factors, or high CVD risk without a moderate-to-high intensity statin prescription. Table 2 provides a list of candidate measures to include in the provider feedback report. We will use an algorithm based on a patient's most recent 2 rheumatology visits to attribute their care to a specific attending rheumatologist (if past 2 visits were with same attending or supervising attending rheumatologist then that patient will be attributed to that attending; if more than one attending was seen during the past 2 rheumatology visits, then the patient will be attributed to the attending with the most recent visits.

We will distribute feedback to rheumatology providers on a quarterly basis along with an achievable high performance benchmark.[19] Dr. Majka and Dr. Ruderman will review these at the Rheumatology Division Meetings. These sessions will also be used to field any questions about the EHR tools and to provide any updates about changes to the EHR tools or work flow. The EHR specialist will be present at the first of these sessions to field questions and feedback about the EHR tools.

Care management: In a fashion similar to what we are currently doing in two ongoing clinical trials addressing primary prevention of CVD in non-RA populations (promoting cholesterol screening and treatment, grant 1P01HS21141 from the Agency for Healthcare Research and Quality), we will employ a non-clinician care manager to perform several functions. We will use repeated queries on an approximately monthly basis of EHR data to determine which RA patients are eligible for care manager outreach based on criteria that include having apparently unmet risk factor screening or preventive cardiology treatment needs, and having an upcoming rheumatology office visit. The care manager will send patients a mailed (or emailed using the patient portal to the EHR) list of topics to review with their rheumatologist or address before the visit. We will also notify rheumatologists of the lists of their patients with scheduled visits in the following week who have been sent these messages. The content will include for each individual patient as appropriate: the recommendation to obtain pre-visit or during visit lab ordering for patients who are not up to date with lipid or DM screening, asking patients to obtain previously-performed external lab results pertaining to lipids or diabetes screening, sending pre-visit CVD risk information to patients who have their risk factors assessed and who may be candidates for statin use, calling attention to elevated blood pressure, and

recommending a smoking cessation attempt in smokers. We will adapt graphic and text risk messages used previously for non-RA patients to suit the specific clinical needs of patients with RA. An example of a CVD risk message (intended for a non-RA patient) is provided in the Figure below.

Table 3. Candidate Measures for Feedback of Preventive CVD Care in RA Patients

Performance measure	Description	EHR data sources
Major CVD risk factors assessed	Proportion of RA patients 40-75 years old with measured total and HDL cholesterol (5 y), glucose or HbA1c (3 y), smoking status, or blood pressure	Demographics, vital signs, smoking field, labs
Adequate statin treatment	Proportion of RA patients CVD or aged 40-75 years with established CVD or an ASCVD risk of $\geq 5\%$ treated with a moderate or high potency statin dose	Demographics, vital signs, smoking field, labs, medication list, problem list
Controlled hypertension	Proportion of RA patients with diagnosed hypertension whose blood pressure was $< 140/90$ (or $< 150/90$ and age ≥ 60)	Demographics, vital signs, problem list
Non-smoking	Proportion of RA patients who are non-smokers	Smoking field
Antithrombotic drug for secondary prevention	Proportion of RA patients with ASCVD who are treated with an antithrombotic drug. Patients with recorded exceptions are excluded.	Problem list, medication list, acknowledgements to best practice alerts

The goal of the care management and outreach is to generate a sense of mutual responsibility whereby the patient becomes activated to pursue the recommended healthcare services or behavior changes to address CVD risk and the rheumatologist—by knowing that patients received this outreach—is activated by the need to meet patient expectations to discuss CVD prevention openly and provide recommended testing and referrals.

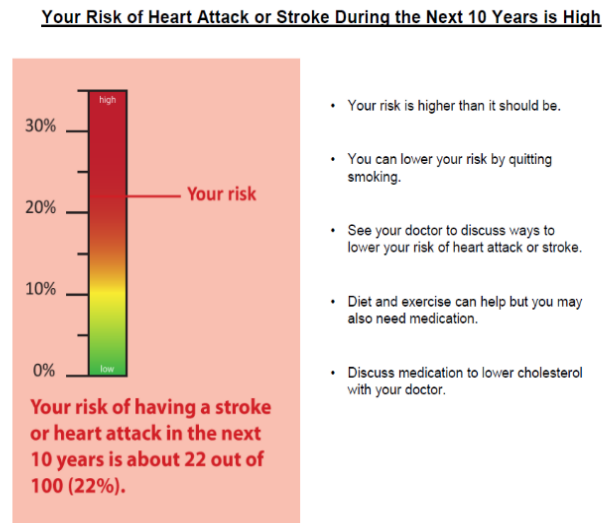
Innovative Aspects of the Design

While referral based cardio-rheumatology clinics have been undertaken in Norway and a few US academic centers,[20, 21] a streamlined systematic approach to CVD risk reduction such as we propose within existing rheumatology and primary care settings has not yet been reported to our knowledge. We have chosen to leverage the rheumatologist-RA patient relationship to improve the identification of unmeasured CVD risk factors or uncontrolled CVD risk because (1) RA patients have frequent contact with rheumatologists, and (2) RA is an independent risk factor for CVD. We have chosen to promote primary care-rheumatology co-management as a model for the delivery of many preventive CVD services because (1) the diagnosis and treatment of hypertension, lipid disorders, diabetes and smoking is well within the purview of adult primary care, and (2) the large majority of this group are primary prevention candidates (without clinically overt CVD) and would not necessarily require ongoing care from a cardiologist or vascular disease specialist. This model also has the advantages of minimizing care fragmentation because it is not necessary to add a new subspecialist to the care team. Lastly our approach attempts to promote explicit communication about roles that are to be played by the different care providers (e.g., rheumatologist can play a key role in identifying CVD risk and promoting risk factor screening and then directly communicate with another provider who may become responsible for further evaluation and treatment of hypertension, dyslipidemia or tobacco use disorders). This feature has been identified as a key component to optimizing the integration of primary and specialty care.[22]

This proposal directly builds on the prior methods Dr. Persell has employed to improve the quality of care delivered in outpatient primary care settings. His prior work includes the detection of unaddressed CVD and DM risk within clinic populations using EHR data,[9, 23] provider directed computerized clinical decision support and performance feedback aimed at improving chronic disease, acute and preventive care topics,[17, 18, 24] and intervention studies to provide patient outreach to address elevated CVD risk,[10] hypertension,[25] and other aspects of care.[24, 26] Dr. Persell is currently leading a randomized controlled trial funded by the Agency for Healthcare Research and Quality using care manager outreach to promote primary prevention of CVD in 3 networks of community health centers in two states.

Within the NMFF delivery system, EHR data can feasibly serve the two broad uses that we will employ in this proposal: 1) the generation of reports that can be used to identify and address the quality of care of whole patient populations, and 2) the generation of point-of-care clinical

Figure. Prototype Outreach Message



decision support features to assist an individual physician caring for an individual patient. As an example of the former, Dr. Persell previously demonstrated that EHR-based identification and a one-time mailed individualized CVD risk message to patients with elevated risk who were not treated with a statin led to significant improvements in statin treatment and LDL cholesterol lowering for primary care patients who were eligible for cholesterol treatment based on the prior ATP III guidelines.[10] This study made use of the same data elements collected within the same Epic EHR system that will be employed for patient identification in the current proposal. We generated the data provided in Table 1 using similar methods applied to RA patients. For the latter, Drs. Persell and Baker and the NMFF information technology group have a long and successful record of designing and implementing point-of-care clinical decision support within the Epic EHR. In the Utilizing Precision Performance Measurement for Focused Quality Improvement study, they implemented point-of-care clinical decision support initially for 16 clinical topics in general internal medicine including cholesterol management and antiplatelet therapy in diabetes and coronary heart disease. (8) Since then, additional clinical topics have been added including hypertension management. Drs. Baker and Ruderman have successfully designed and implemented multiple clinical decision support rules that are currently in use within the NMFF rheumatology practice to support appropriate adult vaccination among RA patients.

Evaluation Design

Outcome Measures

We will measure outcomes using EHR data obtained from Northwestern University's EDW available for the RA patients attending NMFF rheumatology visits. Because this intervention will be done system-wide we will use interrupted time-series modeling (as we did previously [18]) to determine if the intervention improved outcomes more than underlying temporal trends. We will identify RA patients at each point in time who are active patients. RA patients with at least 2 visits in the past 18 months will be included in the assessment at each monthly point in time. There are several outcomes of primary interest that we will follow during the project period. The first is the proportion of RA patients 40 to 75 years old who have all of the following completed: total and HDL cholesterol measured within the past 5 years, glucose or HbA1c measured within the past 3 years, smoking status documented, and blood pressure measured in the past 1 year. The second is the proportion of RA patients 40 to 75 years old with a 10-year CVD risk of at least 5% (based on risk factors[12] or established CVD) who are prescribed a moderate or high intensity statin. The third outcome is the proportion of RA patients 40 to 75 years old who are initially not statin treated and have a 10-year CVD risk of at least 5% who achieve a LDL (or non-HDL) cholesterol reduction of ≥ 30 mg/dL. The fourth outcome is the proportion of RA patients with persistently elevated blood pressure and without prescribed antihypertensive medication or a hypertension diagnosis who receive the diagnosis of hypertension. The fifth outcome is the proportion of RA patients with diagnosed hypertension whose most recent blood pressure was $<140/90$ (or $<150/90$ and age ≥ 60).[14]

Analysis Plan

We will calculate these outcomes for each of the 5 outcome measures for the first of each month from September 1, 2014 through February 1, 2015 to establish the baseline rates of performance. We will continue to assess these outcomes for 18 months following the implementation of the provider education, clinical decision support, provider feedback and care management that will commence in February 2015. This will yield a 24- point time series for each measure. We will fit a linear model to each series using time as a continuous predictor, intervention as a dichotomous indicator variable, and a term for the interaction between time and intervention. Next, we will determine the autoregressive order of the model residuals by minimizing Akaike's information criterion.[27] Then we will fit the linear regression model with autoregressive errors (using the appropriate number of autoregressive parameters, if any are necessary) to each series. We will use these fitted models to tests for statistical significance. [28] We will further analyze changes in outcomes occurring early in response to the intervention (within the first 6 months), between 7 months and 1 year, and after 1 year. We will analyze results through the first 12 months of the intervention in the spring of 2016 and submit these findings to a national meeting. We will include results through 18 months of follow up in the final analyses. Analyses will use SAS version 9.3 (SAS Institute Inc., Cary, NC) and R software package version 0.10-16 (R Foundation for Statistical Computing, Vienna, Austria).[28, 29] We expect to produce the changes stated in the objectives above. However with this sized population, the time-series methods we will use should enable us to detect statistically significant changes that are considerably smaller than these targets.

Rheumatologist Interviews to Assess Engagement and Optimize Delivery System

Approximately 10 weeks after the start of the 18-month care management period, we will conduct interviews with rheumatology practitioners to assess their opinions about the specific components of the intervention, as well as their suggestions for improvement. This will include the eight rheumatologists in the NMFF practice who are not investigators on this proposal. In addition, we will interview the five rheumatology fellows (rheumatologists in training) working with the attending physicians because they will also have utilized the point-of-care tools. Interviews will include structured and qualitative open ended questions aimed at ascertaining rheumatologist's attitudes about the intervention. We will ask respondents to assess the quality and barriers to use of the clinical decision support features in the EHR, educational materials provided for patient education, order sets for cardiovascular risk factor measurement, and template letters for communication with generalists. In addition, the rheumatologists will be queried about the necessity for the assistance of a care manager in identifying and alerting patients in need of intervention, communicating with generalists, and retrieving records of previously measured risk factors and pertinent risk factor treatments provided by generalists. Results of the interviews will be pooled for each question and Drs. Persell and Majka will not know which rheumatologists responded to the questionnaires. Responses will be used to determine whether changes are needed for the Best Practice Alerts, order sets, educational materials, letter templates, or care manager work flows. The responses will also be used to identify needs for any further clarification about the EHR tools and work

flow which could be delivered at the quarterly educational sessions within the Rheumatology Division Meetings. We will use the results of these interviews to refine the intervention tools and procedures during the remainder of the intervention period.

Dissemination Plans

We will disseminate our findings through a number of avenues. Our primary dissemination plan will be to present data from this project in presentations at national meetings followed by journal publications. As we have outlined in the Project Timeline Section and the Analysis Section, we expect to conduct interim data analyses after one year of follow up in February 2016. These preliminary analyses will be completed in time for the American College of Rheumatology National Meeting and the American Heart Association's Scientific Sessions which have June Abstract submission deadlines. The final analyses of the complete data set will be started in August 2016 and we will begin preparing manuscripts in the fall of 2016 so that they will be in submission to scientific journals by the end of 2016. We will also submit an abstract reporting 18-month results to the Society of General Internal Medicine National meeting. Thus, we will be able to quickly disseminate our results to the scientific community.

Should this grant be funded, details of this specific Pfizer Independent Grant for Learning and Change project will be posted on both the Persell and Majka web pages on the Northwestern Scholars website. This website can be accessed via links on each of our faculty web pages. At the beginning of the funding period, Drs. Majka and Persell will give two lectures describing 1) CVD risk in RA, and 2) using HIT and care team change to improve CVD risk. After these lectures are given to the Rheumatology and General Internal Medicine health care provider communities at Northwestern, we will post these sessions on Northwestern University web sites and make them available as free downloads. Available content will include slides with and without audio narration. In addition, the clinical decision support rules and measure specifications used in this proposed project will also be posted on the web and be available to download for free. Finally, we will submit the patient educational materials describing cardiovascular risk in RA to the American College of Rheumatology for consideration to be posted on their patient education website. Of note, the co-investigator, Dr. Ruderman, chairs the American College of Rheumatology's Communication and Marketing Committee which generates and oversees the educational materials posted on that website.

Detailed Workplan and Deliverables Schedule

During the first 5 months of the project period, we will complete the written material and technical specifications needed to implement the project. This includes the written patient education material for inclusion in the clinical decision support, and patient mailings. This will also include a general educational sheet about cardiovascular disease in RA and steps patients should take. During this time we will also fully specify the logic for the clinical decision support rules, provider reports, and care manager protocols. We will produce recorded education sessions for rheumatology and primary care audiences by January 2015.

Starting in February 2015, we will implement the multifaceted intervention. After about two months of the active intervention, we will conduct interviews with rheumatology attending

physicians and fellows. Lessons learned from these interviews will be used to optimize the delivery of the decision support, feedback, and care management. The intervention will continue for a total of 18 months. Quarterly feedback, decision support and care management will continue during this time. We will stop the intervention procedures in August of 2016 and commence analysis. We will conduct initial analyses after 12 months of the intervention has elapsed and prepare presentations for dissemination at meetings. During the final 6 months of the project, we will prepare written manuscripts. We will also finalize educational materials and a technical implementation manual for distribution and dissemination.

Project Timeline

TASK	2014	2015		2016		2017
	Aug-Dec	Q1-Q2	Q3-Q4	Q1-Q2	Q3-Q4	Jan
Create CDS* and feedback report						
Develop care registry and train Care Manager						
Implement CDS, feedback & care management						
Track outcomes						
Analyze changes in outcomes						
Write manuscripts and present at meetings						
Prepare dissemination materials						

*CDS: Clinical Decision Support

Table 4. Project Deliverables

Deliverable	Scheduled Completion
Written patient education material for decision support and print	9/2014
Full specifications for provider feedback report	10/2014
Full specifications for care manager protocol	11/2014
Initial testing of decision support rules, in test EHR environment	11/2014
Educational session, rheumatology audience	1/2015
Educational session, primary care audience	1/2015
Implementation of decision support rules in production EHR environment	2/2015
Obtain baseline monthly outcome measures (3/1/14-2/1/15)	2/2015
Begin quarterly rheumatology provider feedback	2/2015
Begin care management	2/2015
Complete rheumatologist survey	5/2015
Complete revisions to intervention procedures based on physician feedback	6/2015
Complete 12-month intervention follow up	2/2016
Complete analyses of primary outcomes at 12 months	5/2016
Submit report of 12 month findings to national meetings	6/2016
Complete 18-month intervention follow up	8/2016
Complete analyses of primary outcomes over 18-month period	11/2016
Submit manuscript reporting main findings	12/2016
Make implementation materials available	1/2017

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Organizational Detail

Facilities, Resources, and Scientific Environment to Support the Proposed Project

Northwestern University's Feinberg School of Medicine (FSM) offers an ideal, stimulating and intellectually rich scientific environment which fosters interdisciplinary interactions and communication. The institutional environment for conducting interdisciplinary research related to persons with autoimmune diseases is particularly strong in the Division of Rheumatology and the Northwestern University Musculoskeletal Clinical Research Center in Rheumatology, a NIH-NIAMS funded P60. FSM has a robust community of faculty conducting health services research (HSR) to improve quality of care. This includes faculty in the Divisions of General Internal Medicine and Geriatrics (GIM), Rheumatology, and the Center for Healthcare Studies (CHS). This research program occupies approximately 30,000 square feet of contiguous space. GIM has 15 MD and PhD research faculty and over 75 staff who work in this space. The CHS, has 30 core and affiliated faculty from a variety of departments and disciplines. CHS hosts pre- and post-doctoral programs in HSR. There are weekly Work in Progress conferences, a weekly HSR seminar series, and monthly MCRC conferences for faculty across Northwestern to present their work. This helps create a collaborative environment in which people work to develop and refine each other's ideas.

Northwestern Medical Faculty Foundation (NMFF): NMFF is the medical practice for the full-time faculty of the Feinberg School of Medicine. NMFF serves a diverse patient population, which includes approximately 30% African-American and 10% Latino patients and the entire spectrum of socioeconomic status. NMFF has vast experience in using the EpicCare EHR for quality measurement and quality improvement, including design of innovative front-end tools and clinical decision support for both physicians and nursing staff. In addition, Dr. Persell has led and Dr. Majka has been involved in research projects to test the impact of these tools. Note that due to changes within the larger Northwestern system, NMFF is in the process of becoming part of *Northwestern Medicine*. NMFF may be referred to as Northwestern Medicine in some correspondences.

Computing Resources: All Northwestern University faculty, trainees, and staff work on Pentium computers connected by a fiber-optic-cable-based Ethernet backbone. All faculty and staff have access to email, the Internet, Unix research computers, and library services through this superstructure. In addition, the GIM and CHS have a dedicated client-server, Windows NT intranet to facilitate sharing hardware, software, and data resources. To enable clinical and translational research, Northwestern created the Enterprise Wide Data Warehouse (EDW) to consolidate data from all patients receiving care in our healthcare affiliates. This single secure database maximizes efficiency and security, making data available for quality and safety studies and clinical and translational research while allowing monitoring to assure consistency with consents and regulatory requirements. The EDW stores over 2 million patient records extracted from EpicCare and other clinical care systems.

Project Leadership and Organizational Capability

Co-principal investigators Dr. Persell (internal medicine) and Dr. Majka (rheumatology) will lead this project. Dr. Persell will lead the design of the clinical decision support tools, electronic health record (EHR)-supported quality measurement, and conduct of the analyses. Dr. Majka

will have primary responsibility for all clinical issues (e.g., training the care manager, integrating the intervention into the rheumatology clinic workflow, overseeing interface with primary care physicians for risk factor modification, and providing rheumatologists with provider feedback). Dr. Persell and Dr. Majka will jointly develop and present the educational lectures and jointly interpret data and perform manuscript writing.

Staff Capacity

Stephen Persell (Co-Principal Investigator): Dr. Persell is an Assistant Professor in the General Internal Medicine and Geriatrics who has investigated several aspects of preventive cardiology care including the use of EHR data for risk stratification, how different forms of risk communication may influence provider decision making, and the effects of delivering patient-directed CVD prevention messages. He also has experience studying how to best use health information technology, patient directed interventions, and care team redesign to improve the delivery of evidence based care in routine practice. Of particular importance to this proposed study, he leads two large randomized intervention studies employing these methods. The first is a NIH-funded R01 study examining the impact on hypertension control of strategies using IT-supported medication management tools and nurse-led care redesign in 12 community health centers. This study is examining if using low-literacy-appropriate educational strategies embedded in an electronic health record with and without a nurse educator improves uncontrolled hypertension, medication discrepancies, and medication adherence. The second is an AHRQ-funded trial of health IT-supported patient identification and lay outreach to promote appropriate preventive cardiology practices at health centers in two states. The latter study focuses on the identification and outreach to individuals at high risk for the primary development of cardiovascular disease. Dr. Persell has extensive specific experience developing and testing clinical decision support tools in the Epic EHR and the generation of feedback to providers using data queried from electronic health records.

Darcy Majka (Co-Principal Investigator): Dr. Majka is an Assistant Professor in Internal Medicine (Rheumatology) and Preventive Medicine. Her clinical expertise is in Rheumatology and she has training and experience in preclinical autoimmunity, RA ascertainment in cohort studies, and autoimmunity in CVD. As a Rheumatology fellow at the University of Colorado, she helped with the initial study design and data collection in the prospective Studies of the Etiology of RA (SERA) cohort study which examines environmental and autoantibody risk factors in individuals with genetic risk for RA. In that study, she assisted with ascertainment of prevalent RA in the SERA cohort. In addition, she conducted a retrospective study examining the relationship between RA-related autoantibodies measured in stored serum from asymptomatic military subjects and subsequent RA development. As a faculty member at Northwestern, she gained further experience in the conduct of epidemiologic studies in large cohorts through her ancillary studies to the Coronary Artery Risk Development in Young Adults (CARDIA) and the Multi-Ethnic Study of Atherosclerosis (MESA). In those studies, she is evaluating rheumatic disease related autoantibodies as risk factors for subclinical atherosclerosis and clinical CVD. She is also examining the relationship between autoantibodies and race, gender, as well as other cardiovascular risk factors. As the PI of an Arthritis Foundation grant, as well as an NIH-funded R21, K23, and a currently funded R01, she has

developed expertise in data collection in cohort studies, recruiting patients from the NMFF rheumatology clinic, and interpretation of autoantibody and cardiovascular biomarker data. She has published and spoken nationally describing the relationship between rheumatic disease related autoimmunity and CVD risk.

David W. Baker, MD, MPH (Co-Investigator): Dr. Baker is Michael A. Gertz Professor in Medicine, Chief of the Division of General Internal Medicine and Geriatrics, and Deputy Director of the Institute for Public Health and Medicine at the Feinberg School of Medicine, Northwestern University. His research has spanned a large number of areas, including access to health care, racial and ethnic disparities in care, health communication, quality of care for chronic diseases, and use of health information technology for quality measurement and quality improvement. Dr. Baker is currently the Principal Investigator and Director for the Center for Advancing Equity in Clinical Preventive Services, a federally-funded Center for Excellence. He has published over 200 original research articles and book chapters.

Eric Ruderman, MD (Co-Investigator): Dr. Ruderman is Professor in Medicine in the Division of Rheumatology and Clinical Practice Director for Rheumatology at the Feinberg School of Medicine, Northwestern University. His research work has focused on clinical trials of new therapeutics in inflammatory arthritides, with a special interest in biologics. He is the Northwestern PI for the African American Rheumatoid Arthritis Network and co-investigator on a Pharmacogenetics Research Network Grant exploring the use of electronic health records to identify subjects for genomic studies. Dr Ruderman is a vice-chair of Northwestern's IRB and chairs several data safety monitoring boards. He has published over 50 original research articles, book chapters, and review articles.

Tiffany Brown, MS (Clinical Care Manager): Ms. Brown is an experienced project coordinator who has served as the project manager for multiple studies that have employed care team redesign and patient outreach. She managed and performed outreach in a successful intervention study that provided outreach to patients who had not completed an ordered colonoscopy for colorectal cancer screening.[26] Currently, she is the lead project manager for the AHRQ-funded cardiovascular disease prevention project led by Dr. Persell. In this study, she has overseen the delivery of preventive cardiology outreach by several lay care managers in multiple community health centers. Therefore, she is well qualified to assist Drs. Persell and Majka to train the rheumatology providers with the new clinical decision support tools in Epic and to coordinate risk factor screening and referral for risk factor modification.

Ji Young Lee, MS (Programmer-analyst): Ms. Lee has performed multiple complex data queries and analyses for General Internal Medicine investigators. Her experience will allow her to lead efforts to query and analyze study data from Northwestern's EDW. She has experience coding Structured Query Language as will be used to document quarterly risk factor measurement and management to generate quarterly performance reports for the rheumatologists. Most recently, she has conducted similar analyses and performance reports for an RA study led by Drs. Baker and Ruderman, "A Technology-Enabled System to Improve Vaccination in RA Patients".



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NORTHWESTERN
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May 22, 2014

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Dear Darcy and Steve:

It is a pleasure to write this letter indicating our enthusiastic support for your Pfizer Independent Grant for Learning and Change entitled "Leveraging Health Information Technology and Team Change to Improve Cardiovascular Disease Prevention in Rheumatoid Arthritis".

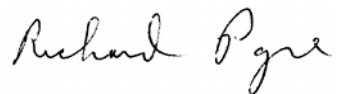
Given that patients with rheumatoid arthritis have a high prevalence of cardiovascular disease and it has been shown that both rheumatologists and primary care physicians identify and manage cardiovascular risk factors less often in rheumatoid arthritis patients compared with controls from the general population, you have proposed a care model to improve cardiovascular disease screening and prevention in rheumatoid arthritis patients. Your proposed intervention will increase cardiovascular disease risk factor assessment, increase rheumatologist counseling about cardiovascular disease risk, and increase appropriate pharmacotherapy for risk reduction by promoting co-management and improving physician-to-physician communication.

We are pleased to assist you with integrating the proposed point-of-care clinical decision support into the existing clinical practice work flow. As the clinical practice director, Dr. Ruderman will provide assistance with trouble shooting as the Electronic Medical Record Best

Practice Alerts are developed and rolled out. He will serve as a co-investigator for your project, and he will devote 1% of his effort for these activities.

We both look forward to working with you on this exciting and potentially groundbreaking project.

Sincerely,

A handwritten signature in cursive script that reads "Richard Pope".

Richard M. Pope, MD
Mabel Greene Myers Professor of Medicine
Chief, Division of Rheumatology

A handwritten signature in cursive script that reads "Eric M. Ruderman".

Eric M. Ruderman, MD
Professor of Medicine
Clinical Practice Director, Division of Rheumatology



May 23, 2014

Darcy S. Majka, MD, MS
Northwestern University Feinberg School of Medicine
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McGaw Pavilion, 240 East Huron St, #M300
Chicago, IL 60611

Dear Dr. Majka,

As the Chief of the Division of General Internal Medicine and Geriatrics, I support of the grant application entitled "Leveraging Health Information Technology and Team Change to Improve Cardiovascular Disease Prevention in Rheumatoid Arthritis" that you and Dr. Persell are submitting to Pfizer. Certainly cardiovascular disease is a common problem among the patients we see in primary care, and we all recognize the need to develop innovative solutions to improve care. Encouraging rheumatologists to identify individuals who are at high risk for cardiovascular disease is likely to be an effective way to promote improved patient outcomes.

Our large primary care internal medicine practice has a long track record of successful participation in studies such as this. We would enthusiastically support educational sessions for our providers at Northwestern Medical Faculty Foundation General Internal Medicine Clinic regarding the relationship of rheumatoid arthritis and cardiovascular disease and its treatments.

I look forward to continuing our work together, and wish you the best of luck. Sincerely,

Sincerely,

A handwritten signature in black ink that reads "David W. Baker, M.D." in a cursive script.

David W. Baker, MD, MPH
Michael A. Gertz Professor in Medicine
Chief, Division of General Internal Medicine and Geriatrics
Feinberg School of Medicine, Northwestern University

May 21, 2014

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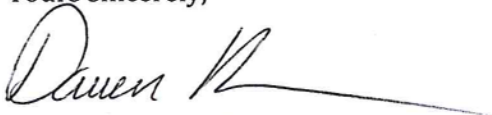
Dear Drs. Majka and Persell:

This letter is to confirm the willingness of the Northwestern Medical Group's Clinical Information Technology group to participate in the study entitled "*Leveraging Health Information Technology and Team Change to Improve Cardiovascular Disease Prevention in Rheumatoid Arthritis*," submitted for consideration to the Pfizer Independent Grant for Learning and Change. The proposed study is an excellent example of how health information technology can be used to deliver high-quality care to specific populations in need, promote team-based care and improve specialist/generalist co-management of patients.

Dr. Persell and I have reviewed the technical aspects of the proposal that would need to be delivered using the Epic EHR. These are all quite feasible.

We have extensive experience delivering clinical interventions using Epic as a platform including extensive prior work with Dr. Persell designing, implementing and disseminating to other sites Epic-based interventions. Notable examples include the Using Precision Performance Measurement to Conduct Focused Quality Improvement (grant 1R18HS17163 from AHRQ), EHR-based Health Literacy Strategy to Promote Medication Therapy Management (NIH grant 1R01NR012745), and Use of Behavioral Economics to Improve Treatment of Acute Respiratory Infections (NIH grant 1RC4AG039115). Our past experience with these and other related projects and our current resources makes me quite confident that we will be able to accomplish the Epic IT objectives necessary to support this project.

Yours sincerely,



Darren Kaiser, MS
Director, Epic Application
Information Systems
Northwestern Memorial HealthCare