# Systems-Based CVD Prevention Protocols for Rheumatology Teams: A low-cost multidisciplinary approach

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#### A2. Abstract:

Tobacco and hypertension are the Centers for Disease Control's "Public enemies #1 and #2" for cardiovascular disease (CVD). Despite recording blood pressure (BP) and tobacco use at rheumatoid arthritis (RA) visits, neither risk is routinely managed. Evidence-based staff-driven protocols in primary care can double tobacco quit rates and increase BP control by 30%, but they have not been used in RA clinics. Our research showed that >2/3 of RA visit BP elevations and >85% of positive tobacco screens went unmanaged. Rheumatologists hesitate to unilaterally manage CVD risk. Primary care providers advise "sending patients back." We thereby propose to refine primary care protocols so that non-physician rheumatology staff will systematically offer brief education and follow-up referrals to primary care for confirmed BP elevations, or for tobacco cessation after positive screening. The proposed quality improvement (QI) intervention enlists rheumatology staff to refine protocols for RA clinics via focus groups and workflow analysis (Objective 1), and implement and assess the hypertension protocol (year 1) and tobacco protocol (year 2) (Objective 2). Lastly, the QI team will evaluate outcomes using controlled statistical analysis of electronic health record data (Objective 3). Evaluations include: (i) system/staff protocol use, (ii) workflow feasibility and staff/patient acceptability, and (iii) outcomes including hypertension and tobacco education, follow-up, and treatment rates. Deliverables include the RA hypertension and tobacco protocols, manuscripts, and electronic toolkit materials for dissemination. This project responds to the call for proposals by empowering real-world RA clinic staff to improve CVD risk modification, predicting strong sustainability and dissemination potential.

#### C3. OVERALL GOALS & OBJECTIVES

Tobacco and hypertension are the Centers for Disease Control's (CDC) "Public enemies #1 and **#2"** as causes of premature cardiovascular disease (CVD) and death. In spite of 50-60% higher CVD risk in patents with rheumatoid arthritis (RA),<sup>2, 3</sup> neither risk factor is routinely addressed in RA clinics. The CDC advocates protocol-driven care which has improved hypertension control from ~50% nationally to 80% in some primary care settings. <sup>4, 5</sup> Similarly, brief (1-3 min) tobacco counseling and or electronic health record (EHR) prompts nearly double quit attempts. 6, 7 Despite routinely recording high blood pressures (BP) and tobacco use in RA clinics, these risks are NOT routinely managed by rheumatologists or non-clinician rheumatology "staff." Our preliminary data from 2,752 RA visit notes (n=1,267 patients with primary and RA care), show that BP elevations were discussed in only 25% of visits<sup>8</sup> and tobacco use in only 13% of eligible RA visits. Moreover, RA visits equaled or exceeded primary care visits for most patients. Although primary care providers (PCPs) are prevention experts, over half of PCPs we interviewed were unaware of elevated CVD risk in RA, making RA visits critical opportunities for identifying and managing such risks. We propose to apply evidence-based staff-driven protocols in RA clinics to increase modification of hypertension and tobacco use. Our proposed quality improvement (QI) proposal directly addresses the aim of this Pfizer program to support "screening for and modification of modifiable CVD risk factors in RA patients."

Our team's long range goal is to improve management of modifiable CVD risk factors as a path to improve the cardiovascular health and survival of patients with rheumatic diseases. In this QI intervention we enlist front-line rheumatology staff to close gaps in identification and management of CVD risks by following routine office BP and tobacco screening with brief protocol-driven education (including lifestyle modification) and coordinated follow-up referrals. We start with these two CVD risk factors as a first step toward a larger program that will address multiple modifiable risk factors. This will lay a foundation to build additional protocols, and for dissemination to other rheumatology practices.

#### Specific objectives for this QI intervention proposal are to:

- 1. Refine evidence-based hypertension and tobacco protocols for specific use in rheumatology clinics to reduce modifiable CVD risks in RA patients.
- 2. Implement rheumatology staff-driven hypertension and tobacco protocols for RA patients and assess feasibility and acceptability at the system and patient levels.
- 3. Evaluate outcomes including completed education and follow-up with primary care or tobacco services before and after the hypertension and tobacco protocol intervention.

**Overview:** This QI intervention project will examine the impact of protocol-based care for hypertension and tobacco use in RA visits at all three UW Health rheumatology clinics. Our multidisciplinary QI team will conduct focus groups with RA clinic staff, and workflow analysis at the three clinics to refine the existing UW Health primary care protocols for use in RA clinics (Objective 1). We will then pilot and implement the refined hypertension protocol in year 1, and tobacco protocol in year 2 (Objective 2). Monthly reports will be provided on clinic staff protocol use for all eligible adult RA visits during the study. Mid-implementation focus groups, workflow analysis, and interviews will evaluate feasibility and acceptability from system and

patient perspectives to inform final RA clinic protocols. Finally, we will compare pre-and post-protocol rates to test whether the modified staff protocols for rheumatology clinic will improve management of hypertension and tobacco including education, timely follow-up, or treatment compared to usual care (Objective 3). Sub-outcome analysis will examine post-protocol changes in systolic and diastolic blood pressures and tobacco quit attempts for example.

UW Health is an ideal setting to carry out this work given our large well-defined RA cohort including many patients receiving primary and RA care in a single system, our expert multidisciplinary team, and our prior research foundation for the proposed QI intervention. This system-based intervention has high potential for clinical impact and future dissemination given its approach to addressing key CVD risk factors in RA patients using real-world clinic staffing. Upon completion, <u>deliverables will include</u>: (1) a hypertension intervention protocol for rheumatology clinics, (2) a tobacco intervention protocol, and (3) two manuscripts and a toolkit of electronic resources for future dissemination to other rheumatology clinics.

#### C4. TECHNICAL APPROACH

#### C4.a. ASSESSMENT OF NEED FOR THE PROJECT

Tobacco cessation remains the most valuable CVD prevention step for smokers. For the 1 in 3 US adults with hypertension, CDC Director Tom Frieden notes, "There is nothing that will save more lives than controlling blood pressure better." Worldwide ≥20% of RA patients continue to smoke and up to 78% have hypertension. 9 In our well-defined cohort of 1267 RA

Table 1. Baseline patient characteristics of UW Health medically homed RA patients with and without hypertension No HTN Patient All HTN Characteristics n=1,267 n=851 n=416 55.4±15.3 59.9±13.5 46.1±14.5 Age (Mean, SD) 20-39 (n=200) 16% 6% 35% 40-59 (n=579)46% 44% 48% 60-79 (n=411) 32% 41% 15% >80 6% Female 75% 74% 78% 57% 64% Married 59% Race/Ethnicity White 91% 91% 90% Black 3% 2% Other/Unknown 6% 8% 6% 87% English Language 86% 83% Medicaid 9% 10% Tobacco Use 11%

patients receiving both primary care and RA care in our network, 11% actively use tobacco, and 67% have hypertension (Table 1). Among hypertensive RA patients 30% were undiagnosed and 60% lacked BP control. We focus on hypertension and tobacco to improve management of these threatening yet modifiable risks through pragmatic staff protocols. If successful, this low-resource intervention to improve modifiable CVD risks in RA could be expanded to include other risk factors, or translated to other rheumatology practices.

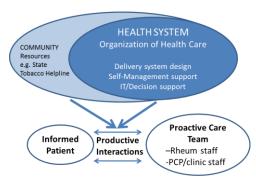


Figure 1. Applying Wagner's Chronic Care Model

Based upon Wagner's Chronic Care Model (Fig 1),<sup>10</sup> we predict that planned delivery system redesign with information technology (IT) support will facilitate proactive team-based care in rheumatology clinics. Such systems will address known gaps in acting on hypertension and tobacco use among RA patients to reduce their CVD risk. Per the CDC, staff protocols succeed by (1) reducing variability, (2) empowering staff (nurses and medical assistants) in improving care, and (3) addressing hypertension (or tobacco) at each encounter to reduce CVD risk factors.<sup>5</sup>

Although protocols have been widely effective improving BP control by up to 30% in primary care, 4,5 virtually no evidence base is available for rheumatology settings. To date, few authors have implemented RA-CVD risk screening as outlined by the European League Against Rheumatism (EULAR). Primdahl et al. in the Netherlands used a nursing outreach model and then referred select patients back for primary care follow-up. Others have performed risk assessments at RA visits, without stated protocols for management or referral. The only published arthritis clinic tobacco intervention was from Spain, where 15% of patients quit and 19% cut back.

#### C4.a.i. Baseline Data Summary and Project Starting Point

This QI proposal is rooted in our prior research that uncovered CVD preventive care gaps for RA patients nationally, <sup>15, 16</sup> and locally within the 12th largest US multi-provider group, UW Health. <sup>8, 17, 18</sup> When we reviewed 2,752 RA clinic notes from those with uncontrolled hypertension, >2/3 of RA clinic notes failed to address this condition even when BPs exceeded 160/100 mmHg. <sup>17</sup> When hypertension was discussed, only 17% of notes mentioned any follow-up. In that study, tobacco recommendations were recorded in 13% of eligible visits (unpublished data). Moreover, among nearly 15,000 UW Health patients with undiagnosed hypertension, RA patients had 29% lower hypertension diagnosis rates compared to non-RA peers despite more visits. <sup>8</sup>

Rheumatology clinics are critically positioned to make system-based changes using modified RA clinic staff protocols for hypertension and tobacco intervention. Our prior national work reporting low lipid testing in RA patients 15, 16 showed that most patients saw their rheumatologist as often or more often than their PCP. Interviews we conducted with RA patients and their providers support our proposed RA clinic intervention. Most patients and PCPs were unaware of elevated CVD risk in RA. 18 Moreover, patients assumed rheumatology would address such issues. As one stated, "I have it [BP] done twice a year in rheumatology, they would say if I had a problem." Rheumatologists were aware of elevated CVD risk, but hesitant to unilaterally manage CVD risk factors including hypertension or tobacco use. Neither rheumatologists nor PCPs used comprehensive CVD risk assessments or formal risk calculators regularly. When we asked PCPs about systems to support RA-CVD prevention in primary care, most indicated that RA occurred so infrequently (estimating 2 visits/mo. versus >50 visits/mo. for rheumatologists) that it would not be practical or important for them. Rheumatologists and PCPs agreed however, that RA clinics could assess key modifiable risk factors and "send patients back" to primary care with RA-CVD risk messages. We therefore propose to refine a protocoldriven intervention to address hypertension and tobacco risk in rheumatology clinics by providing brief education and arranging timely follow-up back to primary care or tobacco cessation services.

**C4.a.ii. Our target audience** is rheumatology clinic teams including medical assistants, schedulers, nurses, administrators and clinicians. To ensure that results can be used by other rheumatology teams, the project will use principles of QI reporting<sup>19</sup> and implementation science.<sup>20</sup>

#### C4.b. PROJECT DESIGN AND METHODS

#### Overview of Design, Setting, and Samples:

This **prospective interventional QI project** will examine the impact of protocol based care upon follow-up of hypertension and tobacco use in RA visits at all three UW Health rheumatology clinics. We will assess visit-level protocol use (fidelity) for all eligible adult RA patients seen at these clinics during the study period. To evaluate patient outcomes, we will use propensity score adjustment on the subset of around 1,267 RA patients receiving both rheumatology care and primary care at UW health to assure controlled analysis (including sociodemographics, comorbidity, and healthcare utilization as covariates) and comprehensive outcome assessment.

#### **Approach Overview:**

As shown in Table 2, first, we will use **semi-structured focus group interviews** to gather feedback to refine proposed protocols with staff input. **QI workflow analysis** will also be used to modify existing UW Health primary care protocols and workflows for use in rheumatology clinic settings to complete Objective 1 and prepare us for protocol implementation. Next, we will sequentially **train**, **pilot**, **and implement the hypertension protocol in year 1**, and then the **tobacco protocol in year 2** in all three clinics (Objective 2). Finally we will **analyze outcomes of hypertension and tobacco intervention protocols** using a pre-post design with propensity matched controls (Objective 3).

Table 2. QI Intervention and A	ssess	sme	nt Ti	meli	ne																				
Activities by Month				Nov	_	Jan '15	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan '16	Feb	Mar	Apr	May	Jun	Jul	Aug'16 - Jan '17
				<u> </u>		Yea												Ye	ear 2						
Objective 1: Refine hypertens	ion a	ınd t	oba	ссо р	roto	cols	for r	heu	mate	ology	/ clin	ics													
IRB (Exemption application)																									
Workflow observation																									
Focus groups		Α				В									C										
Modify protocol workflows																									
Objective 2: Implement and assess hypertension protocol																									
Staff training & 2 week pilot I																									
Implement Clinic 1																									
Clinic 2																									
Clinic 3																									
Monthly audit feedback	Data	a Pre	p									Sustainability monitoring													
Objective 2: Implement and as	sess	tob	acco	prot	tocol																				
Staff training & 2 week pilot II				Ė																					
Implement Clinic 1																									
Clinic 2																									
Clinic 3																									
Monthly audit feedback											Sustainability														
Objective 3: Evaluate outcome	es of	hyp	erte	nsior	n and	tob	acco	pro	tocc	ol int	erve	ntio	ns												•
Final dataset creation					Dataset Planning																				
Analysis						Analysis Planning																			
Manuscript & toolkit prep																									

#### Key strengths of this QI proposal include that it is:

- Evidence-based—adapted from proven primary care protocols<sup>4, 5, 21</sup>
- **Pragmatic**—real world use of protocols enlisting usual rheumatology clinic staff to facilitate management of BP elevations and positive tobacco screens at point-of-care
- **Staff empowering**—elevates professional role of staff while promoting systems change

- Physician-approved—fits preferences of PCPs and rheumatologists
- Implementation-ready—uses existing EHR tools and refines existing protocols

Protocol simplicity and use of common real-world staffing models make this QI intervention both locally sustainable and dissemination-ready for other rheumatology clinic settings.

#### C4.b.i. Objective 1 Approach

1. Refine evidence-based hypertension and tobacco protocols for specific use in rheumatology clinics to reduce modifiable CVD risks in RA patients.

#### **Objective 1 Methods and Analysis:**

The proposed approach is supported by our prior work and existing primary care protocols for hypertension and tobacco used in primary care. This QI intervention will begin by refining protocols for use in the three rheumatology clinics.

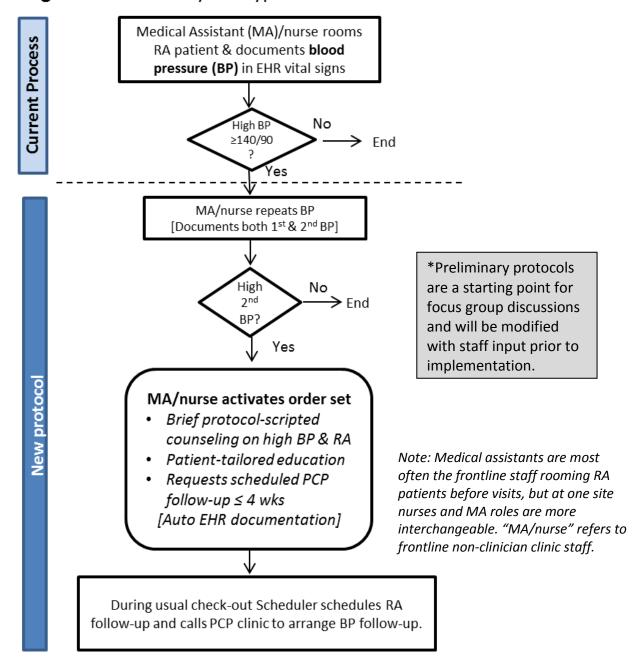
**Focus groups** will seek staff engagement by conducting four focus groups (collectively referred to as focus group Wave A).<sup>22</sup> Each group will have approximately six participants from any of the three clinics. Participants will be grouped by roles (i.e., a medical assistant [MA] focus group, scheduler focus group, nurse focus group, clinician/leader focus group). A trained focus group facilitator will use a semi-structured approach to elicit responses from the group about proposed workflows, and ask them to identify potential barriers and supports. We will review focus group transcripts using *content analysis*<sup>23</sup> per our prior work.<sup>18</sup> Focus groups will be repeated mid-implementation for each protocol to assess feasibility and acceptability. Staff Champions<sup>24</sup> will help with recruitment and member-checking (see letters of commitment).

Workflow analysis & synthesis. Early in the process our consulting QI health systems engineer will perform one week of structured workflow observation<sup>25, 26</sup> in the three clinics. These observations will help adapt the new protocol and workflows for use in rheumatology clinics. We will map baseline MA/nurse BP measurement steps and tobacco screening steps, along with timing these clinical steps for later post-intervention comparison. Findings of the focus groups and workflow analysis will be synthesized by the full research team to revise the primary care hypertension and tobacco protocols for context specific use in the three rheumatology clinics prior to implementation. Two systems engineering tools will be used to analyze and integrate the information collected from focus groups, and workflow observations of front-line staff: swim lane activity diagrams and failure modes and effects analysis.<sup>27, 28</sup>

**The protocols.** The proposed QI protocols are based upon UW Health's primary care adaptation of the Medicare quality hypertension protocol,<sup>21</sup> and a published team-delivery model of tobacco interventions.<sup>29, 30</sup> The **RA hypertension protocol** (Figure 2)will involve standardized MA/nurse assessment with re-measurement of elevated BPs in the rheumatology clinic. If confirmed high, the MA/nurse will provide brief, tailored lifestyle education (eliciting patient

preferences for diet education versus comprehensive BP care) and request scheduling a primary care follow-up visit.

Figure 2. Preliminary RA Hypertension Protocol Intervention



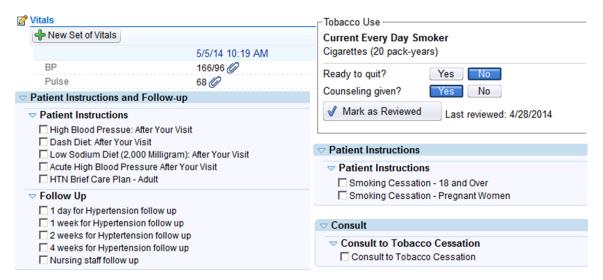
In the RA tobacco protocol (Figure 3), MA/nurses will complete tobacco use assessment and perform scripted education and offering of tailored cessation referral for active users (either clinic or phone consultation.

Medical Assistant (MA)/nurse rooms RA patient & EHR vital signs cue to ask tobacco history Current Process tobacco user? End [Document] No Yes MA/nurse asks about interest in quitting & readiness to quit Brief MA/nurse [Document] counseling No Yes MA/nurse congratulates & opens tobacco order set to offer education and referral to State New protocol Tobacco helpline or consult for Rx Declines Accepts MA/nurse activates MA/nurse activates printing written quit education helpline outreach consent or material to be printed referral + education material with after visit summary [Autodocumented] [Autodocumented]→End √ Scheduler faxes or schedules → End State tobacco helpline contacts patient and sends follow-up fax: Patient accepted, declined, or unreachable; Notes if patient requested single or multi-call follow up counseling and or nicotine replacement. [Study team records]

Figure 3. Preliminary RA Tobacco Protocol Intervention

Workflows and related screen shots of existing EHR tools supporting the two protocol interventions are shown (Figure 4).

Figure 4. Blood pressure and tobacco follow-up screens



The referral for hypertension follow-up or tobacco cessation referral will be automatically routed to the rheumatology scheduler's desk. Upon check out, the scheduler will help the patient schedule rheumatology follow-up. For those with high BP who have UW Health primary care, a follow-up appointment will be made via the scheduler phoning that respective clinic to request a visit with the PCP or nurse within 4 weeks. Patients with PCPs outside UW Health will be instructed to schedule with their PCP at the recommended ≤4 week period as printed on their after visit summaries. Tobacco cessation referrals will be phoned to the UW tobacco cessation clinic, or faxed to the state tobacco helpline by the rheumatology scheduler at the time of clinic check-out as well.

#### C4.b.ii. Objective 2 Approach

2. Implement rheumatology staff-driven hypertension and tobacco protocols for RA patients and assess feasibility and acceptability at the system and patient levels.

#### **Objective 2 Inclusion Criteria:**

This QI project will include visits of adult patients ≥18 years, with a rheumatologist visit for RA, and either (a) a BP reading ≥140/90 mmHg during at least one UW Health rheumatology clinic visit OR (b) a positive tobacco screen. Rheumatology clinic visits meeting these criteria will comprise the denominators to compare performance pre-and post-implementation of the protocol.

#### **Objective 2 Pre-Implementation Planning and Implementation:**

Following workflow analysis and focus group wave A, UWMF/UWHC clinical staff trainers will provide **best-practice training on blood pressure measurement** for front-line staff. This site-specific 30 minutes session will be used to review accurate BP measurement technique<sup>31</sup> with certified trainers. Consistent with norms for these staff, next the study team will deliver a 20-minute **hands-on site-specific training** to teach MA/nurse and scheduling staff to teach new **hypertension protocol workflow steps and tools**. This training will launch a **2-week pilot trial**, which will be staggered by 1 week at each site. Daily onsite support and observation the first week will help make final rapid cycle revisions. Throughout we will use the Plan Do Check Act (PDCA) continuous rapid improvement cycles to refine and evaluate protocols, address performance gaps, and share best practices.

Following completion of the training and pilots at all three sites, **the go-live implementation** for the refined hypertension protocol will be staggered to add one of three clinics every 2 weeks. QI team staff will provide on-site support at least weekly at each site for weeks 1-4. Feedback will be gathered and provided monthly at staff meetings thereafter. Health Innovation Program analyst programmers will **run EHR audit feedback reports** with protocol use data to be shared with clinic staff at monthly staff meetings to promote protocol fidelity.<sup>32</sup>

After 3 months (between two 3-month cycles of the full 6-month implementation period) another midcycle wave of **focus groups (Wave B)** will be conducted. Mid-cycle focus groups will include two groups of 5-6 people, from any of the three clinics. The goals of this wave will be (1) to assess the hypertension protocol acceptability, address barriers and share best practices and (2) to discuss the upcoming tobacco protocol implementation. If focus groups, for instance, describe concerns regarding locating the order sets, then EHR solutions could be sought. The last 3-month cycle would follow, **totaling 6 study months** at each site. Sustainability of the hypertension workflow will be assessed via monthly protocol use reports until the end of the QI project.

In year 2, a brief one-on-one **20 minute staff training will initiate the tobacco intervention** protocol for a **similar 2-week pilot**. MA/nurses and scheduling staff will be taught new tobacco protocol workflow steps and tools and daily help will be available during the pilot period. The official starting dates for the tobacco protocol implementation will be staggered to add one of three clinics every 2 weeks. Protocol use will be monitored for **6 months at each site**. Mid-cycle workflow and **focus group analysis (Wave C)** at month 3 will be repeated to assess feasibility and acceptability, and protocols will be further revised through this summative evaluation. The goals of Wave C include: (1) tobacco protocol and (2) summative assessment.

#### **Objective 2 Data & Analysis:**

For Objective 2 assessment, we will assess feasibility and acceptability of the staff-driven protocols. EHR queries will analyze visits that meet the inclusion criteria for either the hypertension or tobacco protocols, respectively, and will assess the proportion of eligible patients with initiated and completed protocols (as indicated by documented education or scheduled follow-up).

**Mid-intervention focus groups** will be used to assess staff engagement and protocol acceptability, feasibility and refinement needs. The trained facilitator will conduct two staff focus groups while all clinics are implementing the hypertension protocol, and two during implementation of the tobacco protocol. Barriers, facilitators and best practices will be assessed using content analysis as per Objective 1.

**Mid-intervention workflow observation** of MA and schedulers at each site will be used to assess operational function and resource use. This will include staff timing for BP remeasurement and scheduling steps, and for tobacco counseling and referral steps to compare with baseline workflow timing. Cost estimates will be generated using measured time for protocol delivery, EHR frequencies for eligibility and staff resource estimates. Moreover, observation may lead to mid-cycle protocol modifications. If, for instance, unacceptable delays are noted with scheduling via phone with various PCP clinics, then an online scheduling system could be implemented.

Lastly, **randomly selected patients** who have participated in each protocol will also be invited to participate in **semi-structured telephone interviews** to discuss acceptability and usefulness of the intervention. Approximately 30 patient interviews will be completed per protocol. This will complement our preliminary data from n=15 RA patient 1 hour qualitative interviews on RA and CVD preventive care.<sup>18</sup>

To summarize these mixed methods assessments, Table 3 details the measures available upon completion of Objective 2.

Table 3. Protocol Implementation Assessments<sup>20</sup>

System Level Assessment	Assessment Method
1) Staff acceptability	Focus group Waves B & C
2) Resource time, Cost (feasibility)	Workflow & EHR data
<ol><li>Staff protocol use (fidelity)</li></ol>	EHR data (visit level)
4) Sustainability	Focus group & EHR data
Patient Level Assessment	Assessment Method
Patient acceptability	Semi-structured phone
	interviews
<ol><li>Refusal/cancellation rates</li></ol>	EHR data

#### C4.b.iii. Objective 3 Approach

3. Evaluate outcomes including completed education and follow-up with primary care or tobacco services before and after the hypertension and tobacco protocol intervention.

#### **Objective 3 Inclusion Criteria and Control Plan:**

Controlled outcome analysis will include adult RA patients  $\geq$ 18 years, with >1 ICD-9 code for RA (714.0-714.33, 714.4, 714.80, 714.81, 714.89), seeing a UW Health PCP AND rheumatologist, who have EITHER (A) a BP  $\geq$ 140/90 mmHg during at least one UW Health rheumatology clinic

visit OR (B) a positive tobacco screen in the UW system during an observation period RA clinic visit. Rheumatology clinic visits meeting these criteria will comprise the cohort denominators pre- and post-the modified protocol. Follow-up EHR outcome data will be monitored additional months to further assess delayed outcomes, including a change in tobacco use status or time to PCP follow-up after a study period visit and to evaluate sustainability of the proposed intervention protocols (see Timeline, Table 2 p 4.)

Controls will include patients meeting the same criteria in the time period 6 months prior to initiation of respective protocols at the same clinics. Propensity score will improve comparability between the pre- and post-intervention groups. 33, 34

#### **Objective 3 Data & Analysis:**

Multiple EHR data elements will be assessed to analyze outcomes for this QI project. Covariates will include patient socio-demographics, insurance, comorbidities, BP medications, tobacco status, BMI, and baseline annual visits will be obtained from EHR data per our prior work.<sup>8, 35, 36</sup> These will facilitate propensity score matching<sup>33</sup> and multiple variable controls. Provider, clinic, and calendar time will also be included to potentially account for time trends or concurrent system interventions.

Outcome variables will assess BP education and timely BP follow-up at the primary care clinic as defined in Medicare's Group Quality metrics<sup>21</sup> (≤4 wks), and tobacco education and referrals rates (Table 4). As in our previous work, several EHR variables including hypertension diagnosis and treatment, and tobacco use pre- and post-intervention will be examined.<sup>37</sup> Lastly, we will manually record state tobacco help line follow-up reports for assessing tobacco use treatment. We will be able to assess change in tobacco use status as last reported in the EHR.

Table 4. Outcome Measures (Objective 3)									
Hypertension Protocol Outcomes									
Primary Outcome	Management of hypertension evidenced by either documented lifestyle modification education and/or completed follow-up PCP clinic BP measurement in ≤ 4 weeks after the RA visit (Timely follow-up per Medicare Group Practice quality measures)	EHR							
HTN Sub- Outcomes	<ul> <li>Assessment of new diagnosis of hypertension OR</li> <li>Initiation of a new antihypertensive medication</li> <li>Changes in systolic and diastolic blood pressure</li> </ul>								
Tobacco Protocol Outcomes									
Primary Outcome	Management of tobacco use evidenced by documented education or completed tobacco cessation referral	EHR							
Tobacco Sub- Outcomes	<ul> <li>Completed State Tobacco Helpline call and outcomes</li> <li>Initiation of a new tobacco cessation medication</li> <li>Documented EHR quit attempt following a study period RA visit</li> </ul>	EHR/ (Plus Manual audit Helpline f/u forms)							

We will compare pre-and post-protocol outcome rates to test our overall hypothesis that compared to usual care, the modified staff protocols for rheumatology clinic will improve management of hypertension and tobacco use including education and timely follow-up referral. To address the potential for differential selection of the pre-post intervention visit-level cohorts we will use *propensity score matching*. We will model the probability (propensity) of a visit being in the intervention period as a function of predictor variables and their interactions. 33 34

#### **C4.c. EVALUATION**

We use mixed-methods evaluation at many stages of the planned intervention. Data collected from patients and staff regarding protocol acceptability and feasibility (Objective 2) is detailed in Table 3 (abridged below). Moreover EHR data from Objective 3 will evaluate outcomes of this QI intervention as shown in the abridged version of Table 4 below.

#### C4.c.i. Metrics

Table 3. Protocol Implementation Assessments (Abridged)

System Level Assessment	Assessment Method
1) Staff acceptability	Focus groups
<ol><li>Resource time, Cost (feasibility)</li></ol>	Workflow & EHR data
<ol><li>Staff protocol use (fidelity)</li></ol>	EHR data
4) Sustainability	EHR data
Patient Level Assessment	Assessment Method
1) Patient acceptability	Phone interviews
<ol><li>Refusal/cancellation rates</li></ol>	EHR data

Table 4. Outcome Measures (Abridged)

Hypertensic	Data source					
Primary Outcome	Documented lifestyle modification education or completed timely PCP clinic follow-up BP measurement	EHR				
	New diagnosis of hypertension OR	EHR				
Sub-	Initiation of a new antihypertensive medication					
Outcomes	Changes in systolic and diastolic blood pressure					
Tobacco Pro	otocol Outcomes					
Primary Outcome	Documented education or completed tobacco cessation referral	EHR				
	• Completed State Tobacco Helpline call and outcomes	EHR/ (Plus				
Sub- Outcomes	<ul> <li>Initiation of a new tobacco cessation medication</li> <li>Documented EHR quit attempt</li> </ul>	Manual audit Helpline f/u forms)				

#### C4.c.ii. Amount of Change Expected

If we assume based upon our preliminary observation (pre-protocol) that <30% of patients have education or a primary care follow-up of BP recorded in  $\leq$  4 weeks, then 478 visit episodes must be observed to have 80% power to detect an increase from 30% to 45%, with a two-sided test at the level of 0.05. That is, we need 239 visits from the post-protocol follow-up period, and 239 matched from the pre-protocol historical data. If we similarly assume based on preliminary observation (pre-protocol) that 13% of eligible visits with RA patients who smoke will receive education counsel and <1% received tobacco cessation referral, then 182 visit episodes must be observed to have 80% power to detect an increase in tobacco education or referral from 13% to 30%, with a two-sided test at the level of 0.05. That is, we need 91 visits from the post-protocol follow-up period, and 91 matched from the pre-protocol visit data.

We will perform chi-squared tests to compare the pre-post intervention proportional outcomes including education, and timely PCP BP follow-up and tobacco referrals. After propensity score matching pre- and post-protocol cohorts the odds for the composite primary outcome of management of hypertension or tobacco will be calculated using logistic regression. <sup>34, 39</sup> Other sub-outcomes will also be analyzed using descriptive frequencies and chi-squared tests of pre- and post-intervention rates including: new hypertension diagnosis, treatment, and changes in systolic and diastolic blood pressure, as well as tobacco treatment and quit attempts.

#### C4.c.iii. Determining Target Audience Engagement

This QI proposal has an extensive process to engage rheumatology teams and keep them engaged throughout, as supported by change management literature. We begin by seeking multidisciplinary input and continuing to seek input amid both protocol implementation cycles. We have established plans to adapt to feedback after pre-intervention planning and mid-cycle assessments. Ease of recruitment for focus groups, as well as ongoing use of the protocols will reflect staff engagement. Focus group interviews will be able to assess staff engagement in modifying and refining the protocols for rheumatology clinics, and to assess overall acceptability of protocols. Moreover, we will be able to monitor sustainability as indicated by use of the hypertension protocol while implementing the tobacco protocol, or use of either protocol after the tobacco implementation phase.

#### C4.c.iv. Dissemination

Our findings will be disseminated nationally via abstract presentations at the American College of Rheumatology Meeting in 2015 and 2016 and production of at least two manuscripts for publication. When the project is completed it will be disseminated through toolkit sharing through our group's HIPxChange website. The toolkit will include intervention materials created for this QI program so that other rheumatology groups and healthcare organizations can implement it. The site (http://www.hipxchange.org/) offers a platform where we can share EHR protocols, workflows, and other QI tools as well as log interest for future collaborations.

The goal of HIPxChange is to accelerate the translation of new and existing knowledge into clinical practice to improve healthcare delivery and health outcomes, and all tools on the

website are available for free to the public. Several toolkits are also now available on HIPxChange that address a variety of health care topics, and since its launch there have been nearly 500 unique downloads of the toolkits from people in a variety of positions at organizations across the globe. Additionally, once toolkits are posted on HIPxChange, they are typically also submitted for inclusion on other dissemination websites to increase their reach.

**Pitfalls and Alternative Approaches:** While immediate staff engagement through pre-implementation planning focus groups and rapid cycle pilots will offer ample opportunity for modifying our approach early, our implementation and analysis plans also offer several opportunities for alternative approaches if unanticipated challenges emerge. If data delivery lags, manual abstraction can be used to assess protocol use for the first month. If protocol fidelity is low, additional training, reminders, or EHR alerts or hard stops can be added for the latter 3 month cycle. Lastly, we can leverage any observed variation in site-specific performance to examine cultural or staffing differences driving performance changes and we can use this to inform future dissemination efforts to other clinics.

**Regulatory and Legal:** We will apply for a quality improvement exemption with waiver of consent for the proposed QI work through the University of Wisconsin Institutional Review Board (IRB). Similar to our prior IRB exempted projects, we will request permissions to analyze the impact of the QI intervention, and for staff focus groups and patient interviews. The Health Innovation Program analytics team has a long history of exempted UW Health QI work using its password protected server and HIPAA compliant firewall. We will also assure that our staff focus group and patient phone interview consent processes and data management practices are approved, as per our prior qualitative and quantitative work.

#### **C5. DETAILED WORKPLAN & DELIVERABLES SCHEDULE**

Ongoing relationships with clinical and research teams as well as clear plans for meetings and reporting schedules will assure timely completion of this work. As PI, Bartels works both in the rheumatology clinics and onsite with the Health Innovation Program (HIP) data team. She will be able to track both clinic implementation and dataset construction.

Weekly research team planning meetings will be held in the first quarter (months 0-3), and then monthly implementation and analysis meetings will be held throughout the duration of the project. Meetings will be led by Dr. Bartels, with project management support from C. Maxcy, the Project Manager. Monthly performance reports will be reported by study personnel at clinic staff meetings held by the Rheumatology Clinic manager as well.

Following the first full implementation, a final hypertension protocol will be the first deliverable for the project by June 2015, near the end of year 1 (see Table 5). In year 2, tobacco protocol implementation will yield a final tobacco protocol for rheumatology clinics and that will be the second deliverable by February 2016. Next, the analysis phase will yield tools for sharing EHR protocols and clinic workflows as well as analytic algorithms for generating performance reports on study metrics by July 2016. **Ultimately a publication-ready toolkit and at least two manuscript drafts will be completed by January 2017 to share findings of this system-based** 

# QI intervention using staff-driven hypertension and tobacco protocols in RA clinics to facilitate management to reduce CVD risk in patients with RA.

Table 5. Deliverable Timeline																								
Activities by Month	Aug Se	pt Oct	Nov	Dec		Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec		Feb	Mar	Apr	May	Jun	Jul	Aug'16 -
7.00.000.000.000	'14				'15												'16							Jan'17
		Year 1 Year 2																						
Objective 1: Refine hypertension and tobacco protocols for rheumatology clinics																								
Modify protocol workflows																								
Objective 2: Implement and assess hypertension protocol																								
DELIVERABLE-1: Final HTN pro	tocol									*														
Objective 2: Implement and assess tobacco protocol																								
DELIVERABLE-2: Final Tobacco	proto	ol															*							
Objective 3: Evaluate outcomes of hypertension and tobacco protocol interventions																								
DELIVERABLE-3: Toolkit and Manuscript drafts																							*	*

<sup>\*</sup>Please also see Table 2 on p. 4 for detailed workplan schedule.

#### D. ORGANIZATIONAL DETAIL

#### D1 & D2. Leadership and Staff Capacity

Christie Bartels, MD, MS (PI) is an Assistant Professor, Rheumatologist, and a Health Services Researcher whose nearly completed NIH-NIAMS K23-funded work has examined CVD prevention for patients with RA. Bartels has led prior successful UW Health Rheumatology clinic QI efforts guiding the group's first efforts to standardize RA disease activity reporting per American College of Rheumatology (ACR) RA quality indicators. That process included modification of existing ACR RA patient assessment tools, and engagement of medical assistants (MAs) for distributing and recording patient reported measures. The process remains in place to date. At baseline functional assessments were present in <21% of encounters per audits of 2,752 RA notes. More recent audits show up to 80% of RA patients having flow sheet documented functional assessment and disease activity scoring in 2013. The assessment tool and related staff workflows are published on http://www.hipxchange.org/.

Bartels also has completed numerous studies on RA and CVD <sup>8, 15-18, 41, 42</sup> and she has presented her mixed methods research at national American College of Rheumatology meetings. She has also served as an expert international panelist on recommendations for CVD preventive care in RA. The proposed project is a pivotal next step translating her findings into systems-based QI intervention to improve CVD preventive care for RA patients.

Bartels is an experienced clinical rheumatologist and researcher, an established collaborator with an outstanding health services research group, and a leader of an independent research team. She has the necessary clinical, analytic, and leadership skills as well as the team structure and infrastructure support to lead execution of the proposed QI work.

Heather Johnson, MD, MS (Co-I) is a Preventive Cardiologist, and a fellow Health Innovation Program investigator whose NHLBI funded work targets hypertension care in young adults. <sup>35, 36</sup> Johnson co-chairs the UW Health Hypertension Workgroup, and she is physician champion for UW Health Hypertension Clinical Practice Guidelines informing best practices in this study. Johnson and Bartels have collaborated on several prior projects. <sup>17, 35-37</sup> Johnson will participate in monthly meetings including defining key process measures for audit feedback, and variable creation for final analytic dataset construction. She will also help revise protocols and workflows, and review toolkits and manuscript drafts for Objectives 1-3.

**Diane Lauver, PhD, RN, FNP-BC, FAAN (Co-I)** is a Professor of Nursing, and former primary care NP, who offers expertise in

Consultants/Advisors:
Systems Engineering Workflow & Ql Implementation: Ramly Preventive Cardiology Interventions: McBride Primary Care: Steffen

nally known for her work, Lauver tered interventions. She will help wise protocol modifications

Christie Bartels,

MD MS

Rheumatology, HSR

PI

Project Manager

**Courtney Maxcy** 

Rheumatology

**Clinic Staff** 

Champions

Heather Johnson.

MD MS

Cardiology, HSR

Co-I

Diane Lauver, PhD

RN FNP-BC FAAN

Nursing

Co-I

Yingqi Zhao, PhD

**Biostatistics** 

Collaborator

CVD prevention and health promotion interventions. <sup>43-47</sup> Nationally known for her work, Lauver has demonstrated the benefits of nurse-delivered, patient-centered interventions. She will help gather focus group multidisciplinary input from Objective 1, advise protocol modifications including patient education scripts for Objective 2, and will aid interpreting final results.

Yingqi Zhao, PhD (Co-I) is an Assistant Professor of Biostatistics and Medical Informatics with

expertise in causal inference in observational data<sup>48-51</sup> who will direct analysis including propensity score matching for the final controlled analysis in Objective 3. She will attend monthly data and analysis meetings in years 1 and 2 and will oversee a master's level statistician for the final analysis beginning in year 2.

**Courtney Maxcy, BS, (Project Manager)** is an Associate Research Specialist with experience in oversight and management of translational projects. As a former Research Coordinator in the UW Office of Clinical Trials, Maxcy has well-developed skills for promoting and documenting protocol fidelity and oversight of research teams. She has been a valued leader on the Bartels research team including conducting prior qualitative research involving the 3 UW rheumatology clinics. She will devote 50% FTE to the project including scheduling and coordinating focus groups, trainings, protocol revision and implementation, reporting, and meeting planning.

#### **Other Consultants and Advisors**

Patrick McBride, MD, MPH, (Preventive Cardiology Intervention Expert Advisor) is Professor of Medicine and Family Medicine, Co-Director of Preventive Cardiology, and University of Wisconsin School of Medicine and Public Health Associate Dean of Students. McBride is an internationally recognized prevention expert with expertise in research on integrating guidelines into clinical practice and measuring effectiveness of system interventions. He has served on the US Preventive Services Task Force and the National Cholesterol Education Program Adult Treatment Panel committees, and the implementation subcommittee for JNC 8 hypertension guidelines. He will advise protocol design and evaluation, quarterly progress, final protocols, toolkits and manuscript drafts.

**Edmond Ramly, MS, PhD ABD, (Health Systems Engineering Consultant)** will offer clinical QI expertise including workflow analysis (Objective 1). He has healthcare innovation implementation and QI experience with UW Health, WI Department of Health, and Harvard Medical School, <sup>54</sup> as well as health systems analysis experience with RAND corporation. He will help launch the project with initial workflow assessments and rapid cycle consultation during year 1 implementation (Objective 2).

**Kristin Steffen, MD (Primary Care Expert Advisor)** is Associate Professor of General Internal Medicine. She is a hypertension committee liaison who offers primary care perspectives and experience with primary care protocols for pilot planning and interpretation.

Rheumatology Clinic Leadership includes Dr. Kevin McKown, Rheumatology Division Chief, and Mr. Jason Davis, who manages the UW Rheumatology Clinics. They value this QI work, and will facilitate access for protocol training and implementation, as well as offer feedback at regular staff meetings to successfully launch and sustain the proposed work (see letters of support).

Rheumatology Clinic Champions include a senior rheumatology medical assistant and scheduler with >40 years of collective experience at UW Health who have committed to support the proposed work (see letters of support, Benson and Borstad). Both have reviewed preliminary protocols, and agreed to assist with recruiting colleagues for focus group participation and to review future protocol workflow refinements.

**University of Wisconsin Center for Tobacco Research and Intervention (CTRI)** has offered unpaid consultative advising (see support letter) to share best practices, including their experience with Fax to Quit programs and EHR staff-led tobacco cessation protocols.<sup>30</sup>

#### **D1b. ORGANIZATIONAL CAPACITY**

The alignment of priorities, institutional and team strengths, and leveraging of existing resources all promise a success for our proposed quality improvement project.

**UW Health** is among the 12 largest US multi-specialty groups with 1,300 faculty physicians providing **2.2 million ambulatory visits annually** including primary care and specialty clinic visits linked in the same electronic health record (Epic) since 2004. This outstanding data source allows us to comprehensively examine CVD preventive care for RA patients as it is delivered in rheumatology and primary care settings within the network. **Hypertension and tobacco use are current UW Health QI priority areas**, although they have not been targeted in specialty clinics. UW Health supports the proposed work as next steps for modifying existing primary care based protocols and workflows for adoption in rheumatology clinics. This will allow us to leverage existing primary care protocols, workflows, and EHR tools and data.

UW Health supports many QI initiatives through FOCUS-PDCA approaches. They pioneered one of the first nationally certified Maintenance of Certification (MOC) Portfolio Programs for physicians to align their UW Health QI work with national professional MOC requirements.

Three UW Rheumatology Clinics provide >10,000 annual visits through three locations making

Table 1. UW Health Rheumatology Clinics Descriptive										
	Site	Managed	Staffing	Estimated quarterly RA visits						
Clinic 1	West	UWHC	MA rooms	531						
Clinic 2	East	UWHC	MA rooms	96						
Clinic 3	S. Park	UWMF	MA/RN	900						
				1527						

it an ideal setting to test and refine intervention protocols (Table 1). Nearly 1/3 of those visits are for rheumatoid arthritis, and a subpopulation of 1267 patients receive all of their primary and rheumatology care in the network. Bartels has led prior successful rheumatology clinic QI projects at

these sites to improve RA functional status and disease activity monitoring including MA workflows (http://www.hipxchange.org).

The UW Health Innovation Program (HIP) offers extensive programming and analytic capabilities from their contributions to research, public reporting, and ACO analytics since 2006. In collaboration with the robust UW Health Innovation Program health services research and programming group, Bartels and Johnson have published several RA and hypertension EHR studies preliminarily defining the RA cohort and many of the data variables for the proposed work. <sup>8, 35, 36</sup> HIP will provide programming support for multiple time point data collection including monthly performance reports and analysis datasets for outcome assessments.

**UW Department of Medicine (DOM) in the School of Medicine and Public Health** supports several members of this investigative team and >100 total research faculty who bring in ~\$77 million dollars for research annually. DOM is home to the **Center for Tobacco Research and Intervention (CTRI)** which offers tobacco intervention expertise. CTRI, led by Institute of Medicine member Dr. Fiore, has offered unpaid consultative advising (see support letter) to share best practices including their experience with EHR MA-led protocols.<sup>30</sup> The DOM and Rheumatology Division support Bartels' pursuit of rheumatology CVD prevention health services research with tenure start-up funds and a contract pledge to protect 75% of her time for research.

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May 21, 2014

Christie Bartels, MD, MS 808 University Bay Drive, Suite 210, Box 9445 Madison, WI 53705

Dear Christie:

It is with great pleasure that I write to commit my collaboration with you on this proposed Pfizer Independent Grants for Learning & Change project "Systems-Based CVD Prevention Protocols for Rheumatology Teams." As a UW Health preventive cardiologist and NIH-NHLBI funded health services researcher, I share your passion for improving CVD prevention and appreciate the opportunity to collaborate on this work. As you know, I am a physician champion for the UW Health Hypertension Workgroup and a member of the Prevention Chronic Disease Workgroup charged with improving hypertension management throughout UW Health. As you also know, hypertension and tobacco use rank among the most prevalent adult health conditions and are leading causes of death. Yet, in national reports, only about half of adults with hypertension achieve control and many continue to smoke.

It has been a pleasure working and publishing with you through the UW Health Innovation Program on hypertension research since 2012. Our prior work refining hypertension variables and definitions through our working group can easily support outcome assessment for this project. Your preliminary data showing that only 1/3 of RA patients have timely repeated blood pressure readings and 8% of visits with active smokers receive documented counselling shows the need for these protocols seeking to close gaps at the primary and specialty care interface. Addressing elevated blood pressures and tobacco use at encounters is an important first step for RA patients, and really for all patients. Every day, hundreds of elevated blood pressures and positive smoking screens go unaddressed in our system, many of which occur in specialty clinics, and the proposed project offers a systematic approach to improve this.

I will continue to work with you in using Objective 1 qualitative findings to modify the protocols and workflows already adopted by UW Health for primary care to optimize Objective 2 implementation. I will also help with developing the few new variables needed for assessments in Objectives 2 & 3, and in final interpretation and manuscript review. As you know, this proposed work complements ongoing UW Health efforts that currently focus exclusively on primary care. My own federally supported career development research supports 75% protected time, of which I will dedicate 5% effort in-kind support for this related collaboration.

Sincerely,

Heather Johnson, MD, MS

Assistant Professor (Tenure Track)

Department of Medicine, Division of Cardiovascular Medicine University of Wisconsin School of Medicine and Public Health



May 20, 2014

Christie Michels Bartels, MD MS Department of Medicine UW- Madison

Dear Christie Bartels,

I am delighted to collaborate on the Pfizer Independent Grants for Learning & Change project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams." I am committed to serving as a co-investigator on the proposed project. As a primary care nurse-practitioner and researcher who studies health behavior change, I recognize the challenges and opportunities of acting on patient's CVD risk factors, such as elevated blood pressures and tobacco use.

I have enjoyed collaborating with you in designing your proposed, multi-faceted research. If funded, I will continue to collaborate with you on refining your design and executing the planned research. More specifically, I will assist you by (1) eliciting and interpreting input from clinic staff for Objective 1, (2) planning protocols for front-line staff and workflow protocol to optimize staff-patient interactions for behavior change, and (3) addressing unexpected challenges in implementing plans to address Objective 2. I also will attend investigator meetings to assist with refining our protocols and methods, interpreting results, and co-authoring manuscripts.

This project is pragmatic and takes necessary steps to reduce gaps in coordinated care between rheumatology and primary care services for cardiovascular disease prevention in RA patients. Because this project will be based on input from a breadth of clinic staff as "stakeholders", it promises to be highly feasible and acceptable. Because your intervention plans are evidence-based, your clinical outcomes are likely to reduce CVD risks. For these reasons, I can envision your intervention being replicated with relative ease in other rheumatology clinics or extended to address other modifiable risk factors to prevent CVD.

I believe my expertise as a primary care clinician, as a researcher in in evidence-based, health-promoting interventions, and in teaching/mentoring in the School of Nursing make me particularly well suited to contribute to this clinically significant project. I am excited to be a part of this team and contribute to this important research that promises to inform and shape practice.

Sincerely,

Diane Lauver, PhD RN FNP-BC FAAN

Him Lauren

Professor, School of Nursing

#### Department of Biostatistics & Medical Informatics

May 22, 2014

Dr. Christie Bartels, MD MS 1685 Highland Ave #4132 MC 2281 Madison, WI 535705

Dear Dr. Bartels:

I am very happy and committed to collaborating with you on the proposed Pfizer Independent Grants for Learning and Change project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams." As you know, I am an Assistant Professor of Biostatistics and Medical Informatics with expertise in causal inference including prior work with observational datasets. I have won national and international awards based upon these approaches and I look forward to lending my expertise to the proposed project.

I have enjoyed meeting with you over the last 4 months to discuss the design and analysis methods in this proposal. The propensity score matching approach accounting for baseline differences between groups in this pre-post intervention design is extremely well-suited to this QI protocol and controlled outcomes analysis of managing hypertension and tobacco use. As you know, I will oversee methodological planning and supervise master's level statistician, Zhan hai Li, who will execute your final analyses for Objectives 2 and 3. I will attend investigator data and analysis meetings to refine our methods and plan for data delivery to streamline analysis. I will help interpret results and co-author manuscripts.

It is a pleasure working with you on this exciting QI project. This work targeting hypertension and tobacco cessation care protocols for RA patients has strong potential to inform practice change. Moreover, completion of the proposed pilot including feasibility and primary and secondary outcomes will position us well for future dissemination work.

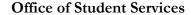
Sincerely,

Yingqi Zhao, PhD Assistant Professor

Department of Biostatistics & Medical Informatics

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May 18, 2014

Dr. Christie Bartels, MD MS 1685 Highland Ave #4132 MC2281 Madison, WI 53705

Dear Dr. Bartels,

I would like to offer you my enthusiastic support and commitment to advise your proposed Pfizer Independent Grants for Learning and Change project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams." As you know, I am a Professor of Medicine, the Associate Dean for Students, and Associate Director of the UW Preventive Cardiology Program. I have been PI on 2 NIH grants to improve the quality of primary care preventive services. We have co-authored 3 papers describing national and local gaps in CVD preventive care for patients with rheumatoid arthritis (RA), and you outline exciting next steps to address these gaps in this proposal.

Examining new strategies to deliver hypertension and tobacco cessation interventions to patients with RA or is both timely and important. As a former primary care physician and preventive cardiology expert, I recognize the challenges of routine prevention delivery that are amplified by disease-specific needs for numerous conditions now known to increase cardiovascular risk. My work serving on national prevention guideline and implementation committees has demonstrated the nuances of providing preventive care to multiple chronic disease populations. Structuring collaboration between rheumatology clinics and primary care partners through protocol driven care is a highly relevant strategy for preventive care delivery that may be tested in the RA population with later applications well beyond this group.

The proposed research is novel and highly relevant as health systems struggle to provide high quality care to growing populations with chronic diseases. Your proposal aligns directly with Pfizer's Request for Proposals seeking to increase active management and modification of CVD risk factors using systems-based QI approaches. You start with two of the greatest modifiable CVD risk factors by addressing known gaps in identifying and managing hypertension and tobacco use, but your proposed protocol methodology will lend itself to adoption for addressing other modifiable CVD risks as well. As we have discussed this is an excellent strategy that leads to action and overcomes the limitations of risk calculation strategies alone, which you have learned through your qualitative work are not being implemented effectively in RA patients.

I will serve as an advisor on the proposed project. My background in Preventive Cardiology, including QI interventional trials in the clinical practice setting, will offer expertise for this QI proposal. I will participate in quarterly progress meetings, and will continue to provide guidance for implementation work, analysis interpretation and manuscript and toolkit review.

I look forward to working with you and believe that you will be a successful leader addressing important future issues in CVD preventive care delivery for RA patients. I strongly support this QI proposal application.

Sincerely

Patrick E. Mc Bil.

Patrick McBride, MD, MPH Associate Dean for Students Professor of Medicine (Cardiovascular Medicine) and Family Medicine Associate Director, Preventive Cardiology May 28, 2014

Dr. Christie Bartels, MD MS

1685 Highland Ave #4132 MC 2281

Madison, WI 53705

Dear Dr. Bartels:

I am very happy to serve as a Health Systems Engineering consultant on your proposed Pfizer Independent Grants for Learning and Change project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams." It has been a pleasure visiting with you over recent weeks to plan the Quality Improvement implementation (QI) and rapid cycle assessment strategies.

As you know, I trained at the Center for Health Systems Research and Analysis (CHSRA), a collaborative effort between the departments of Industrial Engineering and Preventive Medicine at the University of Wisconsin-Madison. My work seeks to improve health systems by developing support systems and facilitating interdisciplinary collaborations in novel and sometimes challenging settings. I have experience in numerous healthcare settings ranging from UW Hospital to community assisted living settings, international medical logistics with the RAND corporation, and evaluation of a national health IT deployment with Harvard.

My expertise includes QI and evaluation of complex interventions, which is well suited to the proposed rheumatology clinic protocol intervention to improve CVD preventive care. I will participate in weekly research team meetings throughout the first year. I will help plan and advise implementation cycles, execute workflow analysis and pilot testing, help facilitate focus group interviews, and advise protocol assessment and revision.

I look forward to working with you on this exciting interdisciplinary QI project.

Sincerely,

Edmond Ramly, MS, PhD candidate

Industrial and Systems Engineering

610 Walnut St, 11<sup>th</sup> Floor Madison, WI 53726 ramly@wisc.edu



May 27, 2014

Christie Bartels, MD MS 1685 Highland Ave #4132 MC2281 Madison WI 53705

#### Dear Christie:

I am pleased to offer my enthusiastic commitment to collaborating with your team on the proposed Pfizer Independent Grants for Learning and Change project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams." As a General Internist with extensive experience on several UW Health quality improvement teams, including groups targeting hypertension and diabetes "shared care," I am wholeheartedly committed to improving such models through rheumatology staff-based hypertension and tobacco protocols. In addition to my role as a General Internal Medicine representative on the hypertension committee, I have also been involved with microsystems changes through the UW Women's health clinic. I will offer these experiences in advising the modified protocol and workflows for specialty clinics.

It was good to meet with you to discuss this proposal and I am enthusiastic about supporting this important QI project aiming to close gaps between primary and specialty care for addressing hypertension and tobacco cessation. You have a sound foundation in your prior studies and recent qualitative results supporting the plan to systematically arrange PCP follow up after elevated RA clinic blood pressures. My practical clinic experience also speaks to how common gaps occur in blood pressure management and how critical it is to address hypertension and tobacco cessation at every visit, even outside primary care.

I plan to be the primary care consultant for your proposed work. As we discussed, I can help integrate qualitative findings into the modified protocol and advise implementation steps based upon my microsystems experience and familiarity with the hypertension committee workflows and tools. I anticipate this will be a highly successful QI project that could be tested in additional RA clinics and other health systems. It will inform national dialogue about managing hypertension and tobacco use in RA patients.

Sincerely.

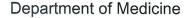
Kristin Steffen, MD

Clinical Associate Professor

Department of Medicine, General Internal Medicine

University of Wisconsin School of Medicine and Public Health

Steffer MD





May 16, 2014

Christie Bartels, MD MS 1685 Highland Ave #4132 MC2281 Madison WI 53705

#### Dear Christie:

I offer my strongest support for your application for the Pfizer Independent Grants for Learning and Change project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams." Patients with RA experience premature cardiovascular events, yet your work shows they receive less CV preventive care including hypertension management, and many continue to smoke. Your QI intervention to improve follow-up and management for hypertension and tobacco use are excellent systems-based approaches that are highly feasible and sustainable.

I have known you for 10 years and it has been a pleasure as your Division Chief to see your growing work in this area. Your QI project for RA disease activity monitoring is among our clinical QI successes as a division. We anticipate similar success with this QI proposal and you have my pledge of support for necessary resources, personnel and access to complete this QI work over the next 2.5 years.

Managing hypertension and tobacco use using a model of rheumatology staff-based protocol-driven care is pragmatic and likely to significantly improve identification and management of hypertension and tobacco interventions. This proposal is timely and important as health teams, including rheumatologists, are called upon to collaboratively improve population health delivery.

In your NIH NIAMS K23, you have reported significant gaps in hypertension diagnosis and follow-up for patients receiving rheumatoid arthritis care from our clinics who also receive UW Health primary care. Your interviews have gathered perspectives of RA patients primary care and rheumatologists. Having completed these observational studies and interviews, you have a solid foundation that makes you ready to complete this QI project. You have also assembled an outstanding multidisciplinary team to collaborate on this important QI work.

I assure you that you will receive full support from the UW Rheumatology Division and our clinic staff. You will have access to all the resources and time to successfully complete the proposed study. I have reviewed the proposal and we have discussed staff engagement and training plans as well as all project timelines and budgets.

Under your K23 you will continue to have a total of 75% protected research time to complete the proposed work, with proportional support shifting to the Pfizer award during the project period. You have demonstrated a sound record of fiscal responsibility with grant management and research team leadership on several prior awards and I offer my full assurance that the resources for this award will be allocated appropriately.

I hope the review committee will share my enthusiastic support for this important QI proposal to improve follow up care of hypertension and tobacco use in RA patients.

Sincerely,

Kevin McKown, MD

Head, Division of Rheumatology

Department of Medicine



West Clinic 451 Junction Road Madison, WI 53717-2656

5/22/14

Dear Dr. Bartels,

As a Rheumatology Clinic Manager for UW West and 1 S. Park locations, I am pleased to offer my strong support your Pfizer Independent Grants for Learning and Change research project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams."

I look forward to working with you to address known gaps in identifying and managing hypertension and tobacco use. I am happy to participate in focus groups, review workflows, and help advise on brief staff trainings and offer you the access, personnel and resources you need to succeed. Our monthly staff meetings are a ready platform for training and feedback. I believe these efforts will also enhance the professional role and satisfaction of our staff.

Recognizing that our rheumatology patients have higher risk for early heart disease events and death, I am excited to be a part of this positive project to help routinely address blood pressure and tobacco usage in our clinics.

Best regards,

Jason Davis

Clinic Manager, Rheumatology—UW Health



## **Health Innovation Program**

### Integrating healthcare research and practice

May 21, 2014

Christie Bartels, MD MS 808 University Bay Dr. Suite 210 Box 9445 Madison, WI 53705

Dear Dr. Bartels:

I am writing to express my strong enthusiasm and support for your Pfizer Independent Grants for Learning and Change project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams." As one of your mentors, it has been a pleasure seeing you translate your work into this exciting research project aimed at improving cardiovascular disease (CVD) prevention for RA patients through modified hypertension and tobacco cessation protocols for rheumatology clinics. Your research will engage specialty staff in improving hypertension and tobacco management and cardiovascular preventive care. The proposed project represents an important step to improve CVD prevention for patients with RA.

As a successful investigator in our Health Innovation Program (HIP), we are committed to supporting this project and your professional development to become an expert in improving hypertension and tobacco interventions for CVD prevention through system interventions facilitating specialty and primary care collaboration. As you know, at HIP we have >10 years of experience with analysis of publicly reported quality metrics, including tobacco and hypertension metrics.

As the Faculty Director of the Health Innovation Program I will ensure that you are provided access to HIP-supported programmer assistance and analysis support, IRB support, and opportunities for feedback on interim progress on subsequent manuscripts that result from this work. In addition, you will have full access to conference room space to meet with project collaborators; on-site office space, which will facilitate contact with other investigators working on similar projects; as well as IT resources, which include access to hardware, software, network, server and intranet resources. The intranet will provide a simple solution to secure file storage and to facilitate file-sharing with consultants outside of the University.

CVD prevalence in RA is a highly relevant and timely topic in light of national priorities targeting group practice quality and it aligns well with HIP goals to innovate and improve healthcare delivery. I fully support you in the proposed research and look forward to working with you in this and future endeavors.

Sincerely.

Maureen A. Smith, MD, MPH, PhD

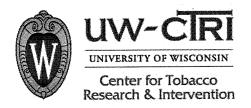
Maureen a Smith

Professor, Dept of Population Health Sciences, Family Medicine, and Surgery

Director, Health Innovation Program

Associate Director – UW Carbone Comprehensive Cancer Center

Director, Community Academic Partnerships Core, Institute for Clinical and Translational Research



May 23, 2014

Dr. Christie Bartels, MD, MS 808 University Bay Dr. Suite 210 Box 9445 Madison, WI 53705

Dear Dr. Bartels:

The University of Wisconsin Center for Tobacco Research and Intervention (UW-CTRI) is pleased to provide tobacco dependence content expertise to you in the event that your Pfizer Independent Grants for Learning and Change quality improvement project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams," is funded. We look forward to advising you regarding best practices to help address the gaps in tobacco cessation care for patients with Rheumatoid Arthritis.

As you know, UW-CTRI is nationally recognized for groundbreaking tobacco research and tobacco treatment training for over 20 years. Beyond studying ways to improve treatment, studies at UW-CTRI are looking at how to improve health system responses to reduce smoking. I know that you have spoken with UW-CTRI investigators who have completed analogous projects using staff protocols and electronic health record tools to increase use of tobacco cessation services.

If your grant application is approved, UW-CTRI will provide relevant content expertise without payment, as this is consistent with our university-wide mission. I wish you well with your important work.

Sincerely,

Michael C. Fiore, MD, MPH, MBA

University of Wisconsin Hilldale Professor of Medicine

Director, Center for Tobacco Research and Intervention (UW-CTRI)

University of Wisconsin School of Medicine and Public Health

1930 Monroe Street, Suite 200

Madison, WI 53711-202

### uwHealth

University of Wisconsin Hospital and Clinics

5/22/14

Dear Dr. Bartels,

I am pleased to offer my strong support as a medical assistant (MA) staff champion for your Pfizer Independent Grants for Learning and Change research project, "Systems-Based CV Prevention Protocols for Rheumatology Teams."

As you know, I have been a senior staff rheumatology medical assistant for the past year, with a >20 year background in primary care and preventive cardiology. I had 13 years of experience in preventive cardiology. I know first-hand the challenges of helping patients address heart risk, and that can be made more challenging when patients are seen in different clinics. I also know that daily in our specialty clinics, numerous elevated blood pressures are recorded by clinic staff without plans for follow-up. I look forward to working with you to address gaps in managing hypertension and tobacco use. I am happy to participate in focus groups, review protocols, and help advise training or other activities.

Recognizing that RA patients have high risk for early heart disease I am happy to be a part of this project to help routinely address blood pressure and tobacco in our clinics.

Best regards,

Joyce Benson

Senior Rheumatology Medical Assistant

**UW West Clinic** 

## uwHealth

University of Wisconsin Hospital and Clinics

5/15/14

Dear Dr. Bartels,

It is a pleasure to offer my support as a rheumatology scheduler staff champion for your Pfizer Independent Grants for Learning and Change research project, "Systems-Based CVD Prevention Protocols for Rheumatology Teams." As you know, I have been a senior rheumatology scheduler for the past year and a half. I have 17 years of experience in UW Health and I am glad to help coordinate care within our health network.

I look forward to working with you to us protocols to close care gaps for hypertension and tobacco use follow-up. I will help recruit and participate in focus groups, review workflows, and advise scheduler trainings.

Sincerely,

Sarah Borstad

Senior UWHC Rheumatology Scheduler