B. Table of Contents

D. Main Section of the Proposal.

D.1. Overall Aim and Objectives. Cardiovascular health (CV health) is a new metric introduced by the American Heart Association in 2010.[1] The metric classifies seven modifiable CV health behaviors and factors into categories of *ideal*, *intermediate*, and *poor* CV health. To date, CV health has not been assessed among older women in primary care settings, although the majority of these data are available in the electronic medical record (EMR).

Adverse health behaviors and health factors are consistently associated with increased cardiovascular disease and stroke risk.[1-3] The four CV health behaviors [smoking status, body mass index (BMI), physical activity (PA), and healthy diet] and three CV health factors (total cholesterol, blood pressure (BP), and fasting plasma glucose) are modifiable. The goal of achieving *ideal* CV health places an emphasis on primordial prevention, or the primary prevention of risk factors,[4] and thus the new CV health metric is useful for assessing the health of Americans of all ages.[5]

The burden of cardiovascular disease and stroke morbidity and mortality is high.[6] Increasing numbers of Americans have overweight/obesity, hypertension, diabetes, and hyperlipidemia.[5] The high cardiovascular disease and stroke burden is likely due to an increase in adverse CV health behaviors, such as unhealthy diet and physical inactivity. From a public health perspective, it is important to identify populations at-risk for cardiovascular disease and stroke.[4] A primary care intervention may serve to raise awareness of stroke risk among providers and patients, particularly in populations assumed to be at low risk for stroke, such as older women. This is an important problem, since management or prevention efforts aimed at stroke may not be routinely offered to older at-risk women in primary care settings.

Our *overall aim* is to decrease the burden of stroke and its modifiable risk factors among older women in primary care practices by leveraging existing health information technology (IT) platforms. Our *central hypothesis* is that an individualized, automated CV health assessment intervention will improve modifiable risk factors for stroke and the treatment of modifiable risk factors for stroke among older female patients in a primary care practice, and the knowledge and awareness of modifiable risk factors for stroke among primary care providers. ***The rationale for the proposed research is that the American Heart Association's CV health metric is evidence-based, has substantial extant infrastructure, and can be readily interpreted by providers and patients in primary care settings***. We plan to test our hypotheses and accomplish the overall aim by pursuing the following *key objectives*:

Objective 1: To examine the effect of an individualized, automated CV health assessment intervention on modifiable risk factors for stroke available in the EMR.

Objective 2: To quantify the effect of an individualized, automated CV health assessment intervention on the ordering of laboratory tests for patients with missing values of cholesterol and glucose, and the pharmacologic treatment of modifiable risk factors for stroke among eligible patients identified via EMR.

Objective 3: To evaluate patient-facing tools that will communicate with existing EMR technologies, and determine if the use of patient-facing tools enhances the assessment of CV health.

Study hypotheses. We will estimate a CV health score among older women in the primary care setting and assess for differences in the mean CV health score pre- and post-intervention (**Objective 1**). We expect that older women will have low CV health scores, and thus are high-

risk for stroke and can benefit greatly from a prevention discussion with their healthcare provider. We anticipate that the intervention will increase the proportion of laboratory tests ordered for women with missing EMR values for cholesterol and glucose at the current appointment (**Objective 2**). We further hypothesize that more eligible patients (those with hypertension, hyperlipidemia, and elevated glucose) will be treated with evidence-based pharmacologic therapies for the control of stroke risk factors post-intervention compared to pre-intervention (**Objective 2**).

An exploratory objective is to identify patient-facing tools that will communicate with existing electronic medical record (EMR) technologies in order to enhance the assessment of CV health (**Objective 3**). We recognize that a barrier to the present-day incorporation of such patient-facing tools in the assessment of CV health is the lack of an interface that allows for data to be communicated seamlessly between a patient-facing tool and the EMR. We will plan to design an interface that is compatible with the needs of primary care providers with input from our clinical and IT collaborators. In addition, these findings will further advance our understanding of how often and why physicians opt out of EMR-based prevention-focused interventions.

Potential impact of the project on patients, providers, and the community. Overall, our anticipated results will add to the extant literature, which contains little information regarding CV health in community-based samples,[1-3] and no CV health data from older women in the primary care setting. The CV health assessment was designed by the American Heart Association to increase awareness of and prevent cardiovascular disease risk factors, heart disease and stroke events, and for the secondary prevention of cardiovascular disease.[1] ***If a CV health assessment is shown to be effective for improving CV health, and identifying and treating risk factors, we will have demonstrated that an intervention with substantial extant infrastructure can lower stroke risk for older women in primary care settings.***

Howard and Goff recently predicted a doubling of incident strokes in the United States from 2010 to 2050, with higher rates among elderly and minorities.[7] This is a serious issue, since our source population comprises elderly women of different race/ethnicities with multiple risk factors for stroke.[8] In addition, management or prevention efforts aimed at stroke may be limited among older women in primary care settings if their CV health is not adequately assessed.[9] ***The proposed study has the potential to increase the awareness of stroke risk among older female patients in primary care practices and their primary care providers using an individualized, automated CV health assessment.***

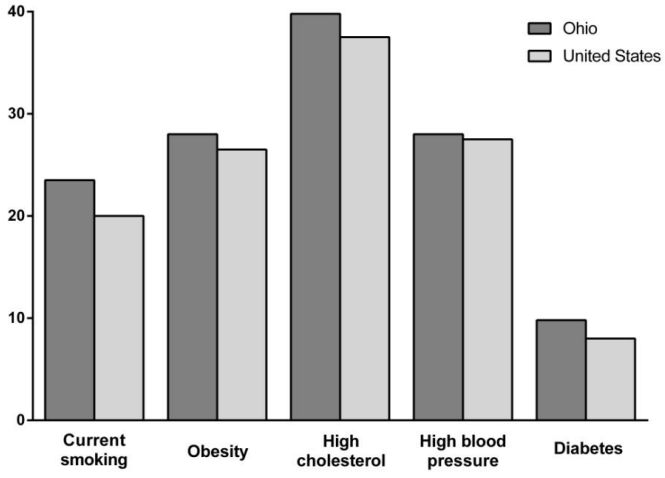
CV health has not yet been used as a clinical tool for the improvement of cardiovascular disease risk factors or their pharmacologic treatment in the healthcare setting.[10] Its potential positive impact on a population of older female patients in the primary care setting is large, since it is estimated that only 3% of older women are in *ideal* CV health on all health behaviors and factors.[10] In addition to attaining the key objectives of this project, our findings will inform future investigations of the effect of reducing the risk of stroke among older female patients in primary care practices, and will help identify the most effective way to overcome physician-identified barriers to such an intervention.

D.2. Current Assessment of Need in Target Area. Heart disease and stroke are the 1st- and 4th-leading causes of death, respectively, among women in Ohio.[11] The *Ohio Plan to Prevent Heart Disease and Stroke* aimed to reduce the burden of heart disease and stroke primarily by

promoting CV health behaviors such as controlling weight, being physically active, living tobacco-free and eating healthy.[11] The *Ohio Plan's* second goal was to reduce high BP, high cholesterol, and diabetes through early detection, treatment, and control of these CV health factors.[11] In the context of the goals set forth by the Ohio Department of Health,[11] the overarching aim of the proposed project is to decrease the burden of stroke and its modifiable risk factors among older women in primary care practices by leveraging existing IT platforms.

Modifiable stroke risk factors that comprise CV health are: smoking status, BMI, PA, healthy diet (fruits and vegetables; fish; whole grains; limiting beverages with added sugar; and lower-sodium foods), total cholesterol, BP, and fasting plasma glucose. Data from the Ohio Behavior Risk Factor Surveillance System (BRFSS, 2009) indicate that many Ohioans are in *poor* CV health (Figure 1).[11] In addition, 74% of Franklin County, Ohio adult residents are screened for high cholesterol and 77% are treated for high BP.[11]

Figure 1. Prevalence of *Poor* CV Health Behaviors and Factors in Ohio and the United States: Behavioral Risk Factor Surveillance System, 2009.



Complementary data point toward a large proportion of Ohio women who are in *poor* CV health according to the modifiable stroke risk factors shown above in Figure 1: 20% of women are current smokers, 29% are obese, 27% report no PA, 73% eat <5 servings/day of fruits and vegetables, 36% have high cholesterol, 26% have high BP, and nearly 7% are diabetic.[11] In these BRFSS data, few women indicated that they had been advised by a physician to: eat less high fat/high cholesterol foods (24%), eat more fruits and vegetables (33%), and increase PA (38%).[11]

These data indicate that there is much room for improvement in CV health among women in Ohio, and there remains a great opportunity for primary care physicians to communicate relevant healthcare advice and take action to reduce the risk of stroke among older women with evidence-based therapies.

The proposed study will be the first to: measure CV health in primary care practices; quantify the effect of an individualized, automated CV health assessment to improve the ordering of relevant laboratory tests and the pharmacologic treatment of modifiable risk factors; and identify patient-facing tools to enhance the CV health assessment in order to identify targets for reducing the burden of stroke among older women. It further aims to quantify the effect of an individualized, automated CV health assessment intervention on modifiable risk factors for stroke, and to inform healthcare systems by determining the influence of patient-provider communication via EMR workflow regarding ideal CV health.

D.3. Technical Approach, Intervention Design, and Methods. *Research design*. We will use a non-randomized intervention design which will allow for a run-in period, comparison group data collection, a provider education period, and implementation of a best practice alert (BPA) to prompt provider-patient interactions regarding CV health.

Timeline. Key dates and implementation of events.

Key dates	Study events
01/01/13-04/30/13	Run-in period
05/01/13-07/31/13	Comparison data collection
08/01/13-08/31/13	Provider education
09/01/13-04/30/14	Intervention
05/01/14-07/31/14	Follow-up data collection
08/01/14-12/31/14	Sustained intervention and data analysis

Study population. Franklin County, Ohio is the home of The Ohio State University Medical Center (OSUMC). The county consists of 120,000 persons ≥65 years of age. Twenty-nine percent of the population is non-white (22% black, 4% Asian, 3% other) and 5% is Hispanic/Latino. Our target population for the proposed project is female patients aged 65 years and older who are seen at CarePoint East, a general internal medicine primary care clinic at the OSUMC. Clinical data from all women meeting the age criteria will be assessed in the current project, regardless of their history of cardiovascular disease or stroke. We recently queried CarePoint East EMR data for the time period of comparison data collection (timeline, above), and we identified over 1,600 women who meet our inclusion criteria.

Theoretical basis for the intervention. The primary audiences targeted for this intervention are: older women in primary care practices, represented in the Chronic Care Model (Figure 2) as the informed, activated patient; and their primary care providers, represented in Figure 2 as the prepared, proactive practice team. We believe the targeted patients, as well as future patients of the targeted health care providers, will directly benefit from this intervention in terms of improved CV health, and the prevention and treatment of modifiable risk factors. We also expect the individualized, automated CV health assessment intervention delivered via EMR to benefit the targeted health care providers by ameliorating barriers to patient-provider communication of stroke risk.

Figure 2. The Chronic Care Model.

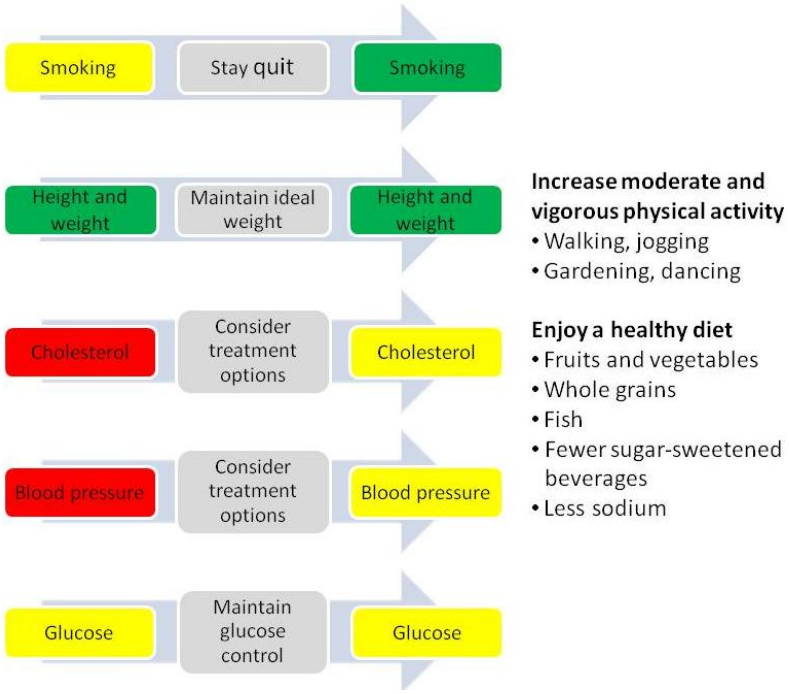
Provider education. Primary care providers are tasked with assisting patients with their acute health issues as well as chronic health conditions. Although guidelines exist for the appropriate pharmacotherapy treatments for stroke risk factors,[12] to date, there is no individualized, automated way to assess stroke risk in the primary care setting. ***The primary care providers at OSUMC are in a strategic position to offer pharmacotherapy for risk factors of cardiovascular disease and stroke.***

The PI will develop provider education materials that are specific to CV health. Provider education will be conducted in two 30-minute sessions during August 2013 (see timeline). The first 30-minute session will be a clinical review of the primary and secondary prevention of risk factors for stroke according to the American Heart Association guidelines for healthcare professionals.[12] An overview of non-modifiable risk factors such as age and race/ethnicity will be discussed, with an emphasis on the established modifiable risk factors of hypertension, cigarette smoke exposure, diabetes, dyslipidemia, obesity, poor diet, and

physical inactivity.[12] In the second 30-minute session, the PI will use case-based examples that include EMR notifications and the use of an external website for facilitating productive interactions between the provider and patient (Figure 2). The primary care physicians and residents will be given an opportunity to briefly role-play the interpretation of a simulated CV health assessment from the external website.

Implementation methods. We will develop a BPA in Epic, our EMR, which will prompt physicians to discuss a patient's clinical CV health score with patients that meet the eligibility criteria. This BPA will be triggered on women age 65 years of age or older who are attending the outpatient primary care clinic at our CarePoint East General Internal Medicine clinic. When the BPA is triggered, the CV health score will automatically be computed using data in the EMR routinely collected as part of usual patient care and display the resulting score to the treating physician. Within the BPA, there will be a link to take the physician to a website outside of the EMR that we will develop to facilitate the educational discussion between the physician and patient regarding the patient's CV health score.

Figure 3. Example visualization of the CV health score.



Our CV health score website will generate visualizations of the CV health score and how each of the input variables would change the patient's CV health score. An example of such visualization is shown in Figure 3. In the figure below, the left column is designed to represent the current CV health of a hypothetical patient given the data pulled from the EMR. In this example, the patient is a former smoker (having quit within the last 12 months), has a normal BMI, but has elevated untreated cholesterol and BP levels, and maintains glucose levels through treatment. The suggestions for improvement or maintenance are shown in gray in the middle column, and the arrow pointing to the right indicates CV health targets for the hypothetical patient: become a former smoker of > 12 months, maintain normal BMI, initiate pharmacotherapy for elevated cholesterol and BP, and continue treatment for glucose levels. In addition to these targets, discussion points are shown on the right side of Figure 3 for increasing PA and enjoying a healthy diet. If the laboratory values for cholesterol and glucose are missing, the BPA will provide an order set so that the provider can efficiently place an order for the assessment of these laboratory values.

Comparison data. Comparison data will be collected from the CarePoint East clinic for three consecutive months as shown in the timeline at the beginning of this section of the proposal. These data will serve as our "control" for the analyses, as they will be collected pre-

intervention. Of note, the follow-up data will be collected one year later during the same three consecutive months to minimize the influence of seasonality on the CV health data and the secondary outcomes of interest (see timeline). Comparison data of interest will include that available from the EMR: smoking status, BMI (height and weight) total cholesterol, BP (systolic and diastolic), blood glucose; orders for laboratory tests for assessing cholesterol and glucose; and treatment for hyperlipidemia, hypertension, or diabetes.

Organizational capacity for meeting the goals of the project. The PI and Co-I are faculty in the OSU College of Public Health. They will obtain pre- and post-intervention CV health, laboratory test orders, and pharmacologic treatment data to assess the outcomes for Objectives 1 and 2 of the proposed project. The PI will additionally develop the education component for the providers at CarePoint East (deliverable).

In order to minimize impact on workflow, the Co-Is in Biomedical Informatics (BMI, OSUMC IT) will do workflow modeling and usability analyses before implementing the BPA in the clinic (deliverable). The Co-I and OSUMC IT will additionally investigate the use of patient-facing tools such as MyChart and Research Electronic Data Capture (REDCap) databases to enhance the future assessment of CV health in the primary care setting (Objective 3).

In addition, the physicians in the CarePoint East General Internal Medicine clinic will be allowed to dismiss the CV health score BPA as he or she deems necessary and to continue other documentation tasks. OSUMC IT will track data on providers who opt to occasionally or permanently suppress all BPAs related to the CV health score, and will assess why the provider has chosen to do so. The additional Co-I's role will be that of content expert for the implementation of the intervention and as representative of faculty at CarePoint East.

Finally, the project manager will be hired through the CCTS, as the CCTS specifically promotes researcher-community partnerships and activities that move scientific findings into the community. The CCTS will leverage its Research Informatics Service to facilitate the completion of the intervention (deliverable) via the OSU Department of Biomedical Informatics, the OSUMC's Information Technology Department, and the Ohio Super Computer Center.

Process evaluation. We will use questions adapted from the American Academy of Family Physicians' journal of Family Practice Management to evaluate the intervention process.[13] We will specifically query the general internal medicine physicians and residents in the intervention clinic regarding the BPA. They will respond to the following statements using the scale *strongly agree*, *agree*, *neutral*, *disagree*, and *strongly disagree*: 1) Overall this BPA is easy and intuitive to use; 2) Documenting care is easy and effective with this BPA; 3) Finding and reviewing information is easy with this BPA; 4) Ordering lab tests, referrals, and imaging studies is easy with this BPA; 5) E-prescribing is fast and easy with this BPA; 6) This BPA provides useful tools for health maintenance (prompts, alerts, and flow sheets); 7) This BPA provides useful tools for disease management (disease-specific prompts, alerts, flow sheets, and patient lists); 8) E-messaging and tasking within the office is easy with this BPA; 9) This BPA enables me to practice higher quality medicine than I could before; 10) I have a good idea how much time this BPA is costing my practice; 11) This BPA is worth the time; 12) The PI and colleagues provide excellent BPA training and support; and 13) I am highly satisfied with this BPA.

Maximizing adherence to the intervention. We will design the BPA according to clinician preferences and input in order to maximize provider adherence to the intervention. The Co-I is a physician in the CarePoint East clinic. She will provide feedback regarding the user-centered design of the BPA. We will additionally collaborate with a consultant physician for the development of the BPA.

D.4. Evaluation Design. *Outcome metrics*. Our ***primary outcome*** is CV health. The modifiable stroke risk factors that comprise CV health are shown in Table 1.[1] Smoking status, BMI, BP, cholesterol, and glucose are available in the EMR for the analysis of Objective 1.

We will define a *CV health score* as the sum of all modifiable stroke factors (Table 1) available in the EMR as follows: poor health, 0; intermediate health, 1; and ideal health, 2. The CV health score will range from 0 (worst) to 10 (best). In order to achieve *ideal* CV health on all measured behaviors and factors, an individual would be a non-smoker (or quit for >12 months); have a BMI of <25 kg/m^2; untreated total cholesterol of <200 mg/dL; untreated systolic blood pressure (SBP) of <120 mmHg and diastolic blood pressure (DBP) <80 mmHg; and untreated fasting glucose of <100 mg/dL.[1]

According to the data from the hypothetical patient presenting to the CarePoint East clinic in Figure 3 and the scoring system described in the previous paragraph, the hypothetical patient would start with a score of 4 out of 10. If this patient achieves the indicated CV health goals with the help of their health care provider, they would achieve a score of 7 out of 10 at their next visit (Figure 3).

Table 1. Measures of CV health in categories of poor, intermediate, and ideal.[1]

Modifiable factors	Poor Health	Intermediate Health	Ideal Health
Smoking status	Yes	Former ≤ 12 months	Never or quit > 12 months
Body mass index	≥30 kg/m^2	25 - 29.9 kg/m^2	<25 kg/m^2
Physical activity	No minutes/week of moderate or vigorous	1-149 min mod, 1-74 min vig, or 1-149 min mod + vig	≥150 min mod, ≥75 min vig, or ≥150 min mod + vig
Healthy diet score	0 – 1 components	2 – 3 components	4 – 5 components
Total cholesterol	≥240 mg/dL	200-239 mg/dL or treated to goal	<200 mg/dL
Blood pressure	SBP ≥140 mmHg or DBP ≥90 mmHg	SBP 120-139 mmHg or DBP 80-89 mmHg or treated to goal	SBP <120 mmHg and DBP <80 mmHg
Fasting glucose	≥126 mg/dL	100-125 mg/dL or treated to goal	<100 mg/dL

Our ***secondary outcomes*** comprise laboratory test orders for patients with missing values of cholesterol and glucose throughout the previous 12 months, and the pharmacologic treatment of modifiable risk factors for stroke among eligible patients identified via EMR. Particular treatments of interest are: BP-lowering medications, cholesterol-lowering medications, and treatments for elevated blood sugar or diabetes. Our ***tertiary outcomes*** include responses to the same questions presented previously in the *Process Evaluation* section, but adapted for provider assessment of patient-facing technologies.[13]

Sources of data. The EMR will be our only source of data for Objectives 1 and 2. We will collect CV health data (Table 1) through usual care, and the most recent outcome metrics, within the previous 12 months, will be accessed for each patient. Through the BPA, we will also track when a physician either decides to opt out of the intervention or if the physician decides to discuss the CV health score with a patient by following the hyperlink embedded in the BPA.

We will also survey all of the physicians in the CarePoint East General Internal Medicine clinic regarding their opinions of the BPA (*Process Evaluation*) and their reasons for either

utilizing the CV health score tool or for ignoring the alert. Objective 3 will explore the feasibility of incorporating data from patient-facing tools such as MyChart or REDCap. The Co-I will use the EMR and patient-facing tools to model the workflow for the attainment of Objective 3.

Statistical methods. Objective 1: To examine the effect of an individualized, automated CV health assessment intervention on modifiable risk factors for stroke available in the EMR.

Analysis of Objective 1 (CV health score) will be done using a linear model approach with generalized estimating equations (GEE) to account for possibly repeated observations on the same women. The outcome (Y) is total CV health score, and the predictor of interest is the time measured, i.e., during the comparison (control) period or during the follow-up data collection period one year later.

Power Calculation for Objective 1. The power calculation is based on a linear model for CV health comparing one intervention to the control; with no predictors in the model and robust standard errors this is approximately equivalent to a t-test with unequal variance. We used National Health and Nutrition Examination (NHANES) data[1] and estimated the variance in the CV health score based on current proportions of the US adult population classified into ideal, intermediate, and poor CV health for each of the 5 health behaviors and factors available in the EMR. Using a two-sided alpha of 0.05, we will have 90% power to detect a mean change of 0.33 unit CV health score (a small, but scientifically significant effect) with 527 women in each group. This sample size is reasonable given that we identified over 1,600 eligible patients in the three-month comparison data period.

Data will be analyzed in aggregate; we will not assess changes pre-intervention to post-intervention among individual women enrolled in an intervention, although we will account for correlation among observations from the same women in the model. In contrast, we will report the mean absolute change in CV health score among eligible women pre-intervention to post-intervention, as this change is meaningful to clinics implementing the intervention in the future.

Objective 2: To quantify the effect of an individualized, automated CV health assessment intervention on the ordering of laboratory tests for patients with missing values of cholesterol and glucose, and the pharmacologic treatment of modifiable risk factors for stroke among eligible patients identified via EMR. We will identify women with missing values for cholesterol and glucose throughout the previous 12 months, and assess the proportion of women for whom laboratory tests are ordered. Similarly, we will identify women who are eligible for and receive pharmacologic treatment of hypertension, hyperlipidemia, and diabetes using the criteria in Table 1, which is consistent with clinical guidelines.[12] Specifically, women in the *ideal* CV health category for each of these three factors will not be eligible, but women who are identified in the *intermediate* and *poor* CV health categories for each of the three factors will be considered eligible for treatment. We will assess for the prescription of medications in three general classes: BP-lowering, cholesterol-lowering, and blood sugar-lowering or diabetic.

Analysis of Objective 2 will be done using a z-test approach to compare proportions. The z-test approach will estimate the difference in the proportions comparing pre- and post-intervention. A significant difference would indicate improvement in the ordering of laboratory tests for patients with missing values of cholesterol and glucose (or the pharmacologic treatment of risk factors among eligible patients) from pre- to post-intervention in the primary care setting. As with Objective 1, data for Objective 2 will be analyzed in aggregate; we will not assess changes pre-intervention to post-intervention among individual women who are missing

data (or who are eligible for treatment). In contrast, we will report the mean absolute change in the proportion of laboratory tests ordered for women with missing BP, cholesterol, or glucose values (or the proportion of eligible women treated with evidence-based therapies for hypertension, hyperlipidemia, and diabetes).

Objective 3: To evaluate patient-facing tools that will communicate with existing EMR technologies, and determine if the use of patient-facing tools enhances the assessment of CV health. Patient-facing tools such as MyChart and REDCap will first be considered for this objective, as both interfaces are utilized at the OSUMC. The use of such patient-facing tools would allow for an individualized, automated CV health assessment to begin when women aged ≥65 check-in for a scheduled appointment with their primary care provider.

Ideally, patients would begin the CV health assessment on a tablet or a secure web portal. Women could skip questions they do not know (i.e., BP values), and complete the assessment with their primary care provider. The patient-facing assessment would prompt the patient to "calculate their CV health score" using their responses. The tablet will display which factors (Table 1) need improvement (red), need attention (yellow), and are currently at ideal levels (green), accompanied by a visual-analog of their CV health score, similar to that shown in Figure 3. At this time, the patient would have the opportunity to e-mail this assessment to an e-mail address they provide using the tablet interface or secure web portal.

The intervention would continue as proposed for the current project: the provider would be prompted to participate via BPA delivered within their EMR. With the additional discrete clinical parameters found in the EMR (Figure 3), the CV health score would be re-calculated. The provider and patient would discuss the revised CV health score and the factors needing improvement (red) and attention (yellow), and the provider will order laboratory tests or prescribe pharmacotherapy for the patient as necessary.

If identification of an appropriate the patient-facing tool occurs within the funding period, we will implement a small pilot of the tool in the Carepoint East General Internal Medicine clinic. We will use the same questions presented previously in the *Process Evaluation* section to query the providers regarding the addition of the patient-facing tool to the BPA intervention.[13] We will score the 13 statements according to published criteria.[13] Additionally of interest will be to query the Co-I and her colleagues regarding whether or not the five-factor CV health metric should be changed to incorporate all seven for clinical purposes.

Strengths and limitations of this approach. Although the concept of overall *ideal* CV health is not new,[1] utilizing a *CV health score* has not yet been demonstrated in the literature. This project will add substantially to the extant literature on CV health and its relevance to the prevention of stroke among older women in primary care practices. The project maximizes the utility of clinical information systems (Figure 2) by pulling relevant data from the EMR on the CV health of older women in the community. This project, by design, is scalable to other primary care clinics and healthcare settings. Specifically, it is estimated that 30-40% of healthcare providers in the United States use the same EMR software (Epic) in which we plan to implement the intervention. Additionally, the patient-facing tools for improving patient-provider communications which we propose to investigate (Objective 3) could be easily adopted in various healthcare settings with diverse patient populations.

For Objective 2, we will assess for the prescription of medications in three general classes: BP-lowering, cholesterol-lowering, and blood sugar-lowering or diabetic medications. We

acknowledge that a limitation of this approach is that these classes of medications have other applications or off-label uses for which we may not be aware.[14] For example, a blood-pressure lowering beta-blocker may be in use for migraine prevention, heart failure treatment, or post-traumatic stress disorder. We will attempt to investigate, among those taking more common types of medication (i.e., propranolol hydrochloride), if the dose is appropriate for the management of hypertension, or if it is below the therapeutic threshold to have an effect on BP. We also plan to assess for co-morbid conditions. Regardless of our non-specific definition of hypertensive medication use, we will be able to observe the real-world usage of these medications in the primary care setting.

Data quality control and data management. With IRB approval, all data on the participants will be stored electronically in the EMR or in a password-protected REDCap study database. The Co-I will maintain the study database in which results of the CV health assessments will be stored. We are aware that these data will contain demographic and personal health information, and we will take consistent measures to protect the confidentiality of these data. These data will all be stored on secure OSUWMC IT maintained computing infrastructure behind the OSUWMC firewall and have been certified by OSUWMC IT to store protected health information. When the data are collected and ready for analysis, the dataset will sent to a Co-I for analysis. Primary care provider satisfaction assessments will be stored in a locked file cabinet in the project office.

Primary audiences. The existing infrastructure of The Ohio State University (OSU) Primary Care Network, the OSU College of Public Health, the OSU Department of Biomedical Informatics, and the OSU Center for Clinical and Translational Science (CCTS) will allow the proposed work to efficiently assess the effect of the intervention and the sustainability of the project in order to reduce the stroke burden among older female residents of our community. In addition, we believe the proposed project is scalable to other primary care practices, and may be used to achieve awareness and treatment of many chronic diseases using our individualized, automated tool and our model of patient-provider communication.

In order to investigate the sustainability of patient-facing tools for assessing CV health (Objective 3), we will again consult with the Co-I and consultant to conduct a review the EMR systems in order to assess whether it would be preferable to create a BPA prompting the provider to collect PA and diet information from patients, or if it would be less disruptive to the clinic visit to use a patient-facing interface such as MyChart or REDCap. In addition, two Co-Is will determine how and where these data will be stored for future accessibility and sustainability of the addition of PA and diet data in the EMR.

Future analyses will allow for additional data collection to assess for the association between the five-factor metric, composed of variables available in the EMR, and stroke outcomes among OSUMC patients. We will then compare the predictive power of the five-factor metric to the seven-factor metric. If the seven-factor metric is more powerful from a predictive standpoint, it will be critical to evaluate and integrate the appropriate workflow for capturing and storing these additional data. If the five-factor metric is equally predictive of stroke risk, the need will not be demonstrated to scale the intervention to incorporate a patient-facing dimension.

E. Detailed Work Plan and Deliverables Schedule.

Work plan for project implementation. We will hire and train project staff, prepare databases and the EMR interface, and finalize project protocol and procedures during the first 4 months of the project period. In year 1 of the project, we will conduct the comparison data assessment of CV health and implement the intervention (**Objective 1**). We will assess pharmacologic treatment of risk factors for stroke (**Objective 2**) for the comparison group in year 1 and from follow-up data in year 2. We will further ascertain physician barriers to providing the intervention in year 2 and identify patient-facing tools for involving patients in the assessment of CV health (**Objective 3**). During year 2, we will conduct follow-up assessments for each objective; enter, audit, and analyze data; present findings; and prepare deliverables.

Schedule for completion of deliverables. We will create a detailed *project summary report* as one deliverable. We will describe the methods, results, limitations, and conclusions for each objective outlined in this proposal. This report will be available to Pfizer medical education staff as soon as the analyses are completed, but no later than the end of the 24-month funding period. We will present a separate *white paper* to the Pfizer medical education staff. The report will contain the following sections: 1) an overview summarizing the CV health metric and describing the overall aim of the white paper; 2) an introduction to the burden of stroke risk among older women in primary care practices; 3) the importance of evidence-based management of stroke risk factors among older women in primary care practices for the prevention of stroke in this population; 4) how individualized, automated assessments of CV health can be promoted in primary care practices; and 5) specific recommendations for primary care that are considering incorporating assessment of the CV health metric in their practice. We will complete the white paper by the end of the 24-month funding period. We will develop and refine the set of recommendations with our consultants to ensure feasibility and scalability.

Separately, we will prepare *policy briefs* for the OSU Primary Care Network. We will summarize the work completed in this proposal in a short report of no more than 2-3 pages for each primary care clinic. We will submit the briefs to the OSU Primary Care Network by the end of the 24-month funding period. Finally, we expect at least one research publication will be submitted to a peer-reviewed journal that publishes cardiovascular research studies (for example, *Circulation* or *Stroke*) that describes the research performed under the three objectives. Additionally, we will submit abstracts for presentations at biomedical informatics, epidemiology, and stroke meetings. The manuscript will be available at approximately the same time as the white paper since we expect to include clinical practice recommendations in the manuscript.

*Institutional Review Board (IRB) Approval***.** The proposed project will require an IRB submission at OSU for expedited review. Given the IRB experience of the investigators, we do not anticipate any problems with the IRB process. The proposed research will require human subject-exempt expedited review for Objectives 1 and 2 because we will be analyzing patient data available from the EMR at an aggregate level, as well as provider process evaluations. Our exploratory objective (Objective 3) ***may*** require an IRB amendment of our original approved application if we are able to identify and implement a patient-facing CV health assessment tool and have the opportunity to pilot it among patients during the 24-month project period. In that case, we would amend the IRB in order to contact and enroll patients for a pilot test of patient-facing tools for the assessment of CV health.

Major tasks and deliverables (with timeline).

Key dates	Major tasks	Deliverables
01/01/13-06/30/13	• Submit IRB application to OSU for expedited review and approval • Train project manager • Prepare BPA and external website • Collect comparison data • Prepare education for practitioners on the CV health assessment tool • Finalize list of clinicians who practice at our intervention clinics	07/01/13: Development of intervention. Program BPA and design external website.
07/01/13-03/31/14	• Analyze comparison data • Educate providers on the CV health assessment tool • Implement intervention • Evaluate intervention process	04/01/14: Provider education and analysis of comparison data.
04/01/14-12/31/14	• Collect follow-up data • Analyze data • Complete final project report, white papers, and briefs • Present findings	12/31/14: Completion of the project. Create summary reports, white papers, and manuscripts.

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