



Virginia Women's Health Stroke Prevention Initiative

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D. Main Section

Overall Aim and Objectives

The proposed work will implement strategies designed to improve primary prevention of stroke in women, with a focus on underserved women. Specifically, through this project, we will:

1. Increase stroke screening in our population of underserved women aged 45 years and older during primary care visits by using a validated screening tool incorporated into the electronic health record (EHR)
2. Increase primary care practitioner management of modifiable stroke risk factors using evidence-based guidelines in appropriate women identified using a validated stroke screening tool
3. Increase awareness of stroke prevention strategies in these women and their primary care practitioners through the use of consumer health information, web-based teaching modules, and other educational programs

Current Assessment of Need in Target Area

Virginia is located within the “Stroke Belt” region of the United States known for the highest incidence and mortality of stroke in the country. Virginia Department of Health data for the City of Richmond indicate that the mortality rate for stroke is 59.3%, as compared to the state rate of 51.1% (age adjusted rate) per 100,000. The City of Richmond leads all Virginia health districts for the highest rates of stroke. Virginia Commonwealth University Health System (VCUHS), located in the City of Richmond, houses the VCU Stroke Center. In 2011, the VCU Stroke Center served over 700 patients admitted for stroke and transient ischemic attacks (TIA), of which 51% were women and 57% were African American. Primary Care Clinic directors report that there are no specific tools used in the clinic to routinely and comprehensively assess patients’ risk for stroke or to encourage management of such risk factors by using evidence-based stroke prevention guidelines.

VCUHS annually serves an average of 10,000 patients in the Primary Care Clinic, averaging a total of 32,000 patient visits per year. In 2011, 61% of Primary Care Clinic patients were African American women aged 45 and older. Notably, African American women are twice as likely to die from stroke compared to Caucasian women. Women at lower socioeconomic levels and those who are uninsured or underinsured are also at greater risk of dying from stroke. VCUHS serves a large Medicaid population, of which Virginia Premier Health Plan (VPHP) a full-service Medicaid HMO owned by VCUHS, provides coverage. As one of the largest Medicaid HMO practitioners in Virginia, VPHP serves 150,000 clients annually, of which women and children represent the majority.

VCUHS primary care patients will immediately benefit from the proposed intervention by receiving education and routine screening for stroke prevention. In addition, patient care will be impacted, as practitioners will utilize standardized training and screening to improve management of modifiable stroke risk factors.

Technical Approach, Intervention Design, and Methods Despite advances in therapies and strategies for stroke prevention, the incidence of stroke remains unacceptably high. The

proposed project will use a multi-pronged approach to improve awareness of, screening for, and management of risks for stroke in a population of underserved women 45 years and older who attend VCUHS's Primary Care Clinic. Specifically, the proposed project is designed to develop materials to educate both patients and practitioners about the risks of stroke, especially in women, and the management of those risks. An electronic stroke screening tool and stroke risk management guidelines will be incorporated into VCU's existing EHR in order to create a sustainable program to promote the prevention of stroke in women.

In this project, stroke screening will be provided for all patients 45 years and older who are seen in VCU's Primary Care Clinic. While this funding announcement focuses on stroke prevention in women, the education programs and screening and risk management tools developed in this project can be used for all patients (women and men) without additional cost, giving the Investigators the unique opportunity to evaluate differences in risk factors, risk levels and treatment patterns between women and men attending the VCU Primary Care Clinic. The clinic provides approximately 2700 patient visits monthly. These patients are equally men and women, predominately African-American (65%) and of low socioeconomic status. Descriptive analyses will be used to evaluate and characterize the total number of patients screened, the number of high-risk patients identified, and the proportion of appropriate stroke risk management recommendations made. Education of patients and practitioners will also be assessed.

Objective 1 – The American Heart Association and the American Stroke Association have published guidelines to help practitioners identify those patients most at risk for stroke and to provide evidence-based interventions targeted at modifiable risk factors in at-risk patients. In the proposed work, VCU's Cerner EHR will be enhanced to provide standardized, routine stroke screening for primary care patients. While the various stroke risk factors have been captured in the EHR during the course of patient visits (e.g., blood pressure is collected as part of the standard vital signs assessment), currently, these data are not collated into a stroke risk assessment using a validated screening tool.

In this project, the investigators will work with VCU's Cerner EHR technicians to program formulas into the EHR that will collate stroke risk data and automatically provide stroke risk scores for all primary care patients aged 45 years and older. These data, including blood pressure, smoking status, cholesterol level, weight, family history of stroke, and presence of atrial fibrillation and diabetes, will be used to stratify patients as being at high, moderate, or low risk of stroke. When patients at moderate or high risk for stroke have scheduled visits with their primary care practitioners, an electronic message in the EHR will alert the practitioners to the patients' stroke risks.

The electronic alert will be programmed by using Cerner Command Language (a vendor specific programming language) by VCUHS information technology (IT) staff (See Budget Justification). The alert will be based on the data elements in the validated National Stroke Association's Stroke Risk Scorecard that can be mapped to the EHR and are represented as rule based logic.

For example, (IF BLOOD PRESSURE > 140/90 THEN ADD 1 POINT TO HIGH RISK SCORE) and (IF HIGH RISK SCORE >= 3, THEN ALERT PROVIDER).

The investigators will pilot test the electronic stroke risk screening program with practitioners from VCU's Primary Care Clinic to determine the best way to provide the stroke risk assessment information to primary care practitioners so that they can effectively and efficiently use the information to improve the health of their patients. The primary care practitioners' recommendations regarding the screening program will be evaluated and incorporated into the final screening tool.

Electronic stroke screening will be implemented for all patients aged 45 years and older who attend VCUHS's Primary Care Clinic. This screening tool will become part of the standard of care in these clinics, and both men and women will be screened for stroke risk. Approximately 800 patients are seen each month in the Primary Care Clinics at VCU. Stroke risk will be calculated electronically in the EHR for each patient and conveyed to practitioners using an electronic alert system. As described below, primary care practitioners at our institution will be provided with order sets to guide them in managing stroke risk. They will also be educated about stroke screening, stroke risk screening tools, and risk reduction for patients who score poorly on stroke risk assessment tools. These practitioners will then be well equipped to evaluate the calculated stroke risk scores and provide recommendations to help patients manage their stroke risks.

Objective 2 – Based on the screening tool, stroke risk will be calculated electronically, automatically documented in the EHRs, and conveyed to the practitioners by using an electronic alert system. For patients who are at moderate or high risk of stroke, the alert will tell the primary care practitioners the patients' stroke risk scores, their stroke risk classification (moderate or high), and their modifiable stroke risk factors. For each modifiable risk factor, there will be "order sets" based on the American Heart Association/American Stroke Association guidelines. The order sets will list the evidence-based guidelines that can be discussed with at-risk patients to assist them in the management of their modifiable stroke risk factors. The recommendations within each order set will be presented as a drop-down list from which the primary care practitioners will select those management strategies discussed with the patients. The selected recommendations will automatically be documented in the patients' EHRs. The order sets will also be programmed by using Cerner Command Language. Different order sets will be programmed for high-risk patients and medium-risk patients. The order sets will be based on evidence-based best strategies for primary stroke prevention, especially in women.

The investigators will pilot test the electronic stroke risk management program with primary care practitioners. The primary care practitioners' recommendations regarding the utility of the program in helping them make appropriate recommendations to reduce stroke risk in at-risk patients will be used to develop the final tool.

The electronic stroke risk screening and alert programs will be monitored on an ongoing basis as part of VCUHS' regular quality improvement program. As part of this project, the investigators will create an electronic monthly report that details 1) the number of patients screened, 2) the number of patients at risk for stroke (medium or high risk level), 3) the primary care practitioner, and 4) the primary care practitioners' electronically documented recommendations to reduce stroke risk.

Objective 3 – Efforts to educate both patients and practitioners about the well-documented and modifiable risk factors as well as non-modifiable risk factors for stroke are integral to preventing this devastating medical problem that is a leading cause of death and disability. In this project, we propose to increase the awareness of stroke risk factors, prevention strategies, signs, symptoms, and the importance of timely treatment of such signs/symptoms with a focus on women through a multi-component educational campaign. For patients, this awareness will be fostered through the use of educational materials distributed through VCU's Community Health Education Center (CHEC) and patient-oriented educational sessions designed and facilitated by the Principal Investigator (PI), who has developed similar sessions in his role as Health Care Disparities representative to the Virginia Stroke Systems Task Force (VSSTF), a collaboration of the Virginia Department of Health and the American Heart Association/American Stroke Association. For practitioners, this awareness will be fostered through a continuing education training module tailored to primary care and focusing on stroke screening and prevention, also designed and facilitated by the PI.

The study team will work with VCU's Community Health Education Center (CHEC) and Primary Care Clinic to provide educational materials about stroke for at-risk patients. Serving the VCU community for more than 10 years, CHEC is a consumer health library that is supported by Virginia Commonwealth University Health System, VCU Libraries and the Medical College of Virginia Hospitals Auxiliary. It provides free, authoritative and accurate health information to over 1300 patients, family members and members of the greater Richmond community each month. For the proposed project, patient-friendly flyers will be developed with information about individual stroke risks, risk management, and signs and symptoms, including information about stroke prevention in women. In addition, a comprehensive list of resources with information about stroke prevention, signs/symptoms, and treatment will be created. This information will also be contained on a webpage that patients can access at CHEC or from their homes.

Clinic patients who are identified as having risk factors for stroke will be given a referral to the CHEC, where they will be able to meet with one of the CHEC librarians to access the patient information sheets, medical texts, and health information websites. Medical prescriptions documenting referrals to the CHEC will be provided by the primary care practitioners to patients. A patient tracking system will be designed and maintained in CHEC, to track patients receiving stroke educational resources in the CHEC.

As an American Heart Association/American Stroke Association award-winning hospital, the VCU Stroke Center currently employs the AHA/ASA 'Get With The Guidelines' (GWTG)

electronic data capture system for acute hospitalized stroke patients. In addition to data collection and analysis, the GWTG system provides the capability to download standardized patient stroke education materials. While the VCU Stroke Center does not currently make use of this GWTG educational component, either for acute hospitalized stroke patients or for outpatient secondary stroke prevention, this GWTG tool will be used in the proposed project as one component of primary and secondary stroke risk reduction education. GWTG patient information handouts, available in both English and Spanish language versions, are directed to general information about stroke as well as stroke warning signs. In addition, the proposed project will incorporate GWTG stroke prevention educational information handouts targeted to patients' specific stroke risk factors such as high blood pressure, diabetes, smoking, life styles, and atrial fibrillation. Patients and their families will also be educated in the use of the AHA/ASA GWTG lay public website, within CHEC.

The proposed project will employ additional patient educational materials derived from other recognized sources, including the National Stroke Association 'Explaining Stroke,' US Department of Health and Human Resources National Institutes of Health/ National Institute on Neurological Disorders and Stroke 'Know Stroke' series, and the Virginia Department of Health Heart Disease and Stroke Prevention Project, Division of Prevention and Health Promotion, publications related to high blood pressure, diabetes mellitus, smoking, and cholesterol.

VCU Medical Center publications including 'Take Action: Know the Warning Signs of Heart Attack, Stroke, and Heart Failure' will also be used. Project team members will develop stroke prevention tools targeted specifically to women to be incorporated into patient and family education efforts in Primary Care Clinics and CHEC.

An example of a resource that will be promoted to patients is the AHA/ASA's F.A.S.T. program (Face, Arm, Speech, Time), an educational initiative designed to help the lay public recognize the signs and symptoms of stroke. Hard copies of patient-oriented educational resources, such as the AHA/ASA's F.A.S.T. campaign materials, will be displayed and accessible to patients in the Primary Care Clinic waiting area. Educational posters on modifiable risk factors, informational brochures and fact sheets will be displayed in the waiting area.

The PI will modify patient-oriented presentations developed in his role as Health Care Disparities representative with the VSSTF and will present a free educational seminar about stroke to the community as part of VCUHS' Medical Seminar Series. This educational presentation will be accessible to patients via a web-based module. The educational video will be posted on the VCU Institute for Women's Health website and accessible via computer stations in the CHEC. This medical seminar series features medical center experts providing important health information, sharing their expertise and answering questions on a variety of current topics in health care. In the session that he presents, the PI will provide information about stroke risks, management strategies, and sign/symptoms, specifically focusing on the stroke risks and burden in women.

The PI will also conduct a patient-oriented presentation in the CHEC to increase awareness of stroke among patients and families by educating on modifiable and non-modifiable risk factors for stroke. Two presentations will be coordinated during the two-year project period. Monthly health education lunch seminars are sponsored by CHEC to educate patients and families on common health issues that impact the Richmond, Virginia community.

To educate VCUHS' 20 attending level primary care practitioners and 50 resident physicians and nurse practitioners, the PI will create an online CE training module tailored to primary care focusing on stroke screening and prevention. The CE module will contain a pre- and post-test and will cover topics including the etiology and pathophysiology of stroke, modifiable and non-modifiable risk factors for stroke, stroke risk assessment tools, recommendations for stroke prevention in at-risk patients, stroke sign and symptoms, treatment options, and the importance of timely treatment. The module will also discuss the differential stroke rate, risks, and outcomes in women. This module will also be posted on the VCU Institute for Women's Health website.

Finally, the PI will excerpt sections of the CE module for a presentation that will be given as part of VCU Institute for Women's Health's "How to Treat a Woman" series. This monthly series of seminars is targeted toward health care professionals to educate VCU's faculty, staff, and students about topics related to women's health.

Evaluation Design

The evaluation plan for this project will involve process and outcome evaluations. These evaluation methodologies will allow the investigators to: a) monitor proper implementation of the proposed activities, b) provide consistent and continuous feedback for timely adjustments, and c) measure program effectiveness using the predefined outcomes.

Process evaluation

An important adjunct to any intervention study is process evaluation. Process data are important to understand the outcome analyses of intervention studies, regardless of the study results. In the context of negative studies, process data can help determine the fidelity of the intervention (or the extent to which the interventions were delivered as intended). In positive studies, a level of specificity in the process evaluation can help scientists understand what elements are required to achieve the beneficial effects of the intervention. To this end, the process evaluation will monitor: a) the extent to which the program is being implemented as designed, b) how well the program is working, and c) the accessibility and acceptability of the program.

The process evaluation will be formative in nature and focus on the timely creation and implementation of the stroke screening and management tools, number of practitioners trained to use the screening, and provider satisfaction with the tools. Additionally, the training will be examined, including dose as measured by attendance at the educational sessions, time spent in the educational sessions, and pre and post assessment of educational sessions.

Data collection tools for process evaluation will be developed and pretested. Tools will include attendance sheets, pre and post assessment surveys for educational sessions, and provider satisfaction surveys.

Outcome evaluation

The outcome assessments will be summative in nature and address the extent to which the project meets its overall objectives. The evaluation team will formally assess the successes of the project by using the following predefined objectives.

Objective 1: By the end of the project, all women aged 45 years older who visit the VCUHS Primary Care Clinic will be screened for stroke using a validated screening tool incorporated into the EHR.

Objective 2: By the end of the project, 90% of the trained primary care practitioners will utilize and adhere to the evidence-based guidelines for appropriate management of modifiable stroke risk factors

Objective 3a: By the end of the project, 40% of women primary care patients aged 45 years and older will visit the VCU Community Health Education Center to receive consumer health information, web-based teaching modules, and other stroke prevention educational resources.

Objective 3b: By the end of the project, 90% of primary care practitioners will be knowledgeable about screening for stroke and management of risk factors.

Indicators will include percent of women screened within the EHR, percent identified at-risk, and number provided with stroke prevention education. Additionally, provider knowledge and

adherence to the evidence-based management using the evidence-based strategies will be measured.

Measures and data collection tools

Electronic Health Record (EHR): The screening tool and treatment plan will be incorporated into the EHR (CERNER software). The number of women who were screened and their risk levels will be captured from the EHR. In addition to identifying patients at risk of stroke, the enhanced CERNER software will keep a log of the alerts so that investigators can examine how often physicians provided the recommended care.

Pre and Post Surveys: Pre and post surveys to assess the practitioner knowledge before and after the trainings will be assessed using an electronic survey.

Satisfaction surveys: The level of satisfaction with the screening tool among practitioners will be examined by using an electronic survey. The survey will be conducted at the beginning (3 months after project implementation) and at the end of the study.

All data including data from the EHR will be captured in the widely used and established REDCap Electronic Data Collection System hosted by VCU. REDCap is a secure, web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g., for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The Evaluation Director will design the pre- and post-surveys in REDCap. She will also regularly monitor the data from the REDCap and EHR systems to facilitate reporting and analysis and perform regular data quality checks within and across these systems including missing value checks.

Data Auditing and Security

Since data will be collected directly from the practitioners in an electronic form, data quality checks (such as data types and range checks) will be performed in real-time, and subsequent data entry by study staff is not required, thus removing several potential levels of error. The Evaluation Director will issue monthly reports to the study team regarding any data missing from the EHR that requires manual follow-up. This regular monitoring and subsequent follow-up will facilitate delivery of a clean and complete dataset for analysis. The web and database servers will reside on centralized VCU servers behind the University's firewall. Web-accessible systems will be protected by appropriate security measures that utilize Secure Sockets Layer (SSL) encryption for transport security. Data storage will be centralized, with regular off-site back-ups performed by trained IT personnel. Only the investigators and other approved personnel will have access to study data, at a level commensurate with their responsibilities.

Data analysis plan

Descriptive analysis including frequencies and proportions will be calculated to determine the proportion of women screened, adherence to standard of care, stroke awareness among practitioners and patients. The number of practitioners trained, based on completion of a post-

test, will be assessed. Pre and post-intervention data will be compared to assess provider knowledge using McNemar chi square tests.

Interim analysis will be conducted for early decision on both utility and efficacy after the first three months of the intervention followed by quarterly reports. Final analysis will be conducted at the end of the project period.

Secondary analyses will be conducted to compare data between women and men attending the VCU Primary Care Clinic. Differences in types of risk factors, risk levels, and treatment patterns will be compared using chi square test and p-values. Multiple logistic regression analyses will be conducted to control for confounding factors that might affect the associations. Potential confounding factors may include but are not limited to race, ethnicity, and age. Adjusted odds ratios and 95% confidence intervals will be used to evaluate sex differences in the study population.

Dissemination

Project results will be widely disseminated to practitioners, patients, and insurance providers. The PI will disseminate the work to practitioners, patients and the lay public through his work with the VSSTF. The co-PI directs VCU's Institute for Women's Health (IWH) and will disseminate findings through an expansive professional and community listserv, at the Annual Women's Health Congress, which is internationally-attended by practitioners, payers, and policymakers, and at the VCU Women's Health Research Day, which is attended by practitioners, faculty, students and community partners. Findings will also be disseminated through peer-review journal publications.

This project will be expanded throughout VCUHS by making the EHR screening enhancements active in all units, system-wide promotion of educational resources in CHEC and promotion of the Continuing Education (CE) module developed by the PI to all practitioners. Education regarding primary prevention of stroke with a focus on women will also occur through VCUHS's mandatory annual practitioner training program, a hospital-wide, web-based education program. Through our partnership with Virginia Premier Health Plan, we will expand the project to a larger network of Medicaid insured Virginia Premier Health Plan sites across the state.

E. Detailed Work Plan and Deliverables Schedule

The proposed project will be implemented within a 2 year project period, from January 1, 2013 to January 31, 2015.

January – June 2013: Development/integration of the screening and management tools into the existing Cerner EMR and development of the patient/primary care practitioner educational material.

Ensuring the step up and implementation of the EHR screening enhancements is essential to the success of this project. The first six months will be dedicated to weekly project team meetings, to include the lead primary care practitioner and Information Technology team members responsible for security and management of the VCUHS Electronic Health Records system (CERNER).

The PI and the CHEC Librarian, will meet regularly during the first six months to review and identify education resource gaps in the library's existing collection of resources relevant to stroke prevention. After assessing existing resources, new educational materials will be selected from national and private organizations with expertise in stroke prevention and patient-oriented resources addressing modifiable and non-modifiable risk factors. A web administrator will also be consulted to upload new educational resources to both the VCU Community Health Education Center and VCU Institute for Women's Health websites.

The PI will modify his practitioner and patient-oriented presentations to develop video educational modules. He will work with VCU production services to record presentations in web appropriate formats.

The Project Coordinator will work with the lead primary care practitioner to promote the project among primary care practitioners targeted in this project and to set up educational displays in the Primary Care Clinic, to coincide with the educational displays in the CHEC.

July 2013: The test runs will be conducted throughout July of the EHR system updates to ensure that technical glitches are identified and resolved prior to implementing the pilot.

August, 2013 to September, 2014: Full project implementation and data collection

The first 60 days of the full project implementation will focus on educating the primary care practitioners about the new EHR screening tool and the availability of stroke prevention guidelines for care management. This will be conducted through primary care practitioner and clinic leadership engaging practitioners through staff meetings and routine staff training. Medical prescription pads will be disseminated to practitioners and they will be encouraged to refer patients with elevated to high stroke risk scores, based on the screening tool, to CHEC for educational support materials. Practitioners will also be encouraged to review the CE module on-line, designed to increase awareness of risk factors and management guidelines among practitioners.

The PIs and the CHEC Librarian, will work to coordinate two dates for the patient and lay audience educational presentations in the CHEC. Dates will be selected based on national health observances and the availability of the CHEC. Thirty days prior to each presentation promotional materials, to include hard copy and electronic flyers will be disseminated throughout VCUHS and community partner networks.

The PIs will work with the VCU Institute for Women's Health Education Committee to coordinate an educational presentation as part of the "How to Treat a Woman" series. One presentation will be conducted during the project period.

The Project Coordinator will setup educational displays in the CHEC and the Primary Care Clinic patient waiting area. Weekly inspections will be conducted in each location to maintain resource supplies.

The Project Evaluator and Information Technology staff will conduct monthly audits of the EHR screening tool and run monthly reports to monitor system functionality and practitioner behaviors related to integration of screening tool in standard of care practices.

The CHEC librarian and support staff will be available daily to assist patients seeking stroke prevention educational resources. All patients will be encouraged to view the patient-oriented video in CHEC.

October, 2014 – January, 2015: Analyze and disseminate data

The project evaluator and information technology staff will retrieve EHR data and run analytic reports to determine project outcomes. Outcome and process evaluation analysis will be conducted and a final report produced.

A final report including the full evaluation report will be submitted to Pfizer at the completion of the project.

Upon completion of the final report the team will identify at least two peer-reviewed journals to which they will submit articles detailing project outcomes. Also, the team will identify local and national professional conferences at which to present findings via poster presentations.

An executive report will be written and disseminated through our local partnership networks.

At the conclusion of the project, meetings will be convened with VCUHS administrators and Virginia Premier Health Plan administrators to move forward with project expansion.