

**Pfizer Medical Education Group
Request for Proposals (RFP)
*Prevention of Stroke in Women***

I. Background

The mission of the Pfizer Medical Education Group is to accelerate the adoption of evidence-based innovations that align the mutual interests of the healthcare professional, patients, and Pfizer, through support of independent professional education activities.

The intent of this document is to encourage organizations with a focus in healthcare professional education and/or quality improvement to submit letters of intent (LOIs) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need. The RFP model is a two stage process: Stage 1 is the submission of the LOI. If, after review, your LOI is accepted, then you are invited to submit your full program proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer Medical Education Group website (www.Pfizermededgrants.com) as well as those of other relevant organizations and is sent via e-mail to internal lists of all registered organizations and users in our grants system.

II. Requirements

Date RFP Issued:	9/13/12
Clinical Area:	Women’s Health
Specific Area of Interest for this RFP:	<p>Design and implement a comprehensive learning and change strategy that promotes the prevention of stroke in women. The program should be implemented in primary care settings and should incorporate current guidelines and utilize electronic health record (EHR) technologies. Learning and change components should target both primary care providers (PCPs) and women. The impact of the program should be assessed by measuring changes in relevant clinical outcomes as outlined in the below section “Recommendations and Target Metrics”.</p> <p>The main focus of the intervention should be the primary prevention of stroke in women. Secondary prevention of stroke in women may also be addressed. Stroke types that are within scope of this RFP include ischemic and hemorrhagic stroke.</p> <p>The successful proposal will provide an individualized, woman-oriented approach to stroke prevention that can be incorporated into the routine healthcare of midlife and elderly women. The major goal of the program should be to increase the diagnosis and appropriate management of modifiable stroke risk factors among women in primary care settings. Examples of program components through which this goal may be achieved</p>

include education of PCPs and women; public service announcements; EHR alerts; stroke risk factor screening programs; and referrals to services specializing in risk factor management such as smoking cessation and weight loss clinics.

Other suggested aims of the program include:

- Increasing primary care provider (PCP) awareness of the burden of stroke among women
- Improving PCP identification of women at increased risk of stroke, utilizing validated stroke-risk assessment tools. Examples of such tools include the Framingham Stroke Risk Profile, the CHA₂DS₂-VASc score in women with atrial fibrillation, and the ABCD² score in women with a history of transient ischemic attack (TIA)
- Increasing PCP awareness of possible differences in presenting signs and symptoms of stroke in women compared to men
- Increasing women's adherence to lifestyle choices and pharmaceutical treatments aimed at reducing the risk of stroke
- A large percentage of women are unaware of the risk factors for stroke and how stroke may be prevented. Many women, particularly those of certain minorities, are not familiar with signs and symptoms of stroke, which may delay stroke diagnosis and treatment and contribute to poorer outcomes following stroke¹.
 - The proposed program should take into account unique healthcare-related challenges faced by women. For example, women often act as the primary caregiver for their families, and may prioritize obtaining appropriate healthcare for their family members over obtaining healthcare for themselves.
- Demonstrating a positive clinical impact of the program

Programs must describe how they directly impact patient care and provide evidence of scalability (e.g., integration with an electronic health record system) and a plan for extension beyond the proposed institution and its specific patient population. The American Heart Association's Get with the Guidelines is an example of a quality measure-based program that has demonstrated scalable improvements in the cardiovascular care of patients.

Disease Burden Overview:

According to guidelines for the primary prevention of stroke published by the American Heart and American Stroke Associations, approximately 795,000 people have a stroke each year in the United States².

- Stroke is a deadly disease. It is the third leading cause of death in the US, after heart disease and cancer, resulting in 134,000 deaths a year². On average, someone dies of a stroke every 4 minutes³.
- Stroke is also a leading cause of functional impairment, with 20% of survivors requiring institutional care after 3 months, and 15% to 30% being permanently disabled².
- In 2010, the total direct and indirect costs of stroke in the US were estimated at \$73.7 billion, with a mean lifetime cost of \$140,048².
- Effective prevention is the best approach for reducing the burden of stroke. Primary prevention is particularly important because 77% of strokes are first events².
- Implementation of stroke prevention measures is imperative following occurrence of a transient ischemic attack (TIA). Individuals who have experienced a TIA are at high risk for a recurrent cerebrovascular event. Between 10-15% have a stroke within 3 months, with half of these strokes occurring within 48 hours⁴.

Stroke is a significant healthcare problem among women:

- According to 2012 stroke statistics from the American Heart Association, women have a higher lifetime risk of stroke than men, estimated at 1 in 5 versus 1 in 6, respectively³.
- Each year in the US, 425,000 women suffer a stroke, 55,000 more than men³.
- Outcomes following stroke are generally poorer in women compared to men:
 - Women account for the majority of stroke deaths in the US. In 2008, women accounted for 60.1% of stroke deaths³.
 - Although the overall death rate for stroke has declined in recent years, declines in stroke death rates observed in women have been lower than those observed in men².
 - Women are more likely than men to experience poorer function and quality of life after stroke⁵.
 - Women are less than half as likely as men to achieve independence in activities of daily living following stroke³.

In the setting of atrial fibrillation (AF), results from large cohort studies and randomized trials suggest that female gender is an independent risk factor for stroke, conferring a relative stroke risk of 1.5-1.9. The etiology of elevated stroke risk in women with AF is likely to be multifactorial and include biological and psychosocial elements. Differences in clinical risk profiles and in the management of stroke risk factors between women and men may contribute to the elevated risk⁶. Underutilization of oral anticoagulation treatment among women may be a contributing factor⁷. Anticoagulation treatment reduces stroke risk in women, with similar bleeding risks to those in men. Clinicians should be aware of the elevated stroke risk associated with female gender in the setting of AF. Management of women with AF should include aggressive treatment of modifiable stroke risk factors and effective anticoagulation as appropriate⁶.

**Gaps Between
Actual and Target
and Possible
Reasons for Gaps:**

The program should aim to address the following gaps in stroke care for women:

1. Inadequate awareness of stroke burden and stroke risk factors in women

Many PCPs are not adequately aware of the risk of stroke in women, which may result in sub-optimal diagnosis and management of stroke risk factors.

Furthermore, women may report different stroke symptoms than men, such as sudden face and limb pain and sudden hiccups¹. Inadequate healthcare provider awareness of possible differences in presenting signs and symptoms of stroke in women compared to men may lead to delays in delivery of appropriate treatment to women and to poorer outcomes.

There is a need for stroke education among women. According to the National Stroke Association, stroke kills twice as many women as breast cancer every year. However in a 2010 survey of women sponsored by HealthyWomen, the National Stroke Association, and the American College of Emergency Physicians, respondents stated that breast cancer is five times more prevalent than stroke. Forty percent of respondents said they were only somewhat or not at all concerned about having a stroke in their life. Seventy percent of respondents said they were not at all or only somewhat knowledgeable about stroke risk factors. Only 27% of women could name more than 2 of the 6 primary stroke symptoms. Inadequate knowledge of stroke symptoms could be one reason why women are less likely than men to arrive at the emergency department within the critical 3 hours following stroke. African American women suffer significantly higher number of strokes than Caucasian women and tend to have poorer outcomes following stroke, yet African American and Hispanic women were less aware of stroke causes and symptoms than Caucasian women^{1,3}.

2. Inadequate diagnosis and management of stroke risk factors in women

Women have unique risk factors for stroke, including pregnancy, use of oral contraceptives and hormone therapy, and greater prevalence of HTN and atrial fibrillation in older ages compared to men^{8,9,10}. Among stroke risk factors common to women and men, diabetes and metabolic syndrome appear to increase the risk of stroke in women to a greater degree than they do in men^{5,11}. On average, women are older at the time of stroke than men (approximately 75 versus 71 years, respectively)³. Overall women experience more cardioembolic strokes whereas men have more atherothrombotic strokes⁹, which may impact acute treatment and long-term follow-up decisions and secondary stroke prevention measures.

Clinicians have consistently underestimated stroke risk in women, and tend to diagnose stroke risk factors less promptly and manage these risk factors less aggressively in women compared to men^{12,13}. Risk factors for stroke including HTN and hyperlipidemia have been found to be more poorly controlled in women compared to men¹⁴. Women experiencing a stroke are less likely than men to receive optimal, guideline-based stroke treatment than men, including antiplatelets, statins, and tPA^{5,9}. Secondary stroke prevention is particularly important among women, as women with first-ever ischemic stroke have a higher risk of stroke recurrence than men⁸.

Recommendations and Target Metrics:	<p>The impact of the program on the rates of diagnosis and appropriate management of modifiable stroke risk factors in women in primary care settings should be assessed. Such risk factors include hypertension, cigarette smoke exposure, diabetes, atrial fibrillation, dyslipidemia, carotid artery stenosis, physical inactivity, and obesity. Impact of the program on the rates of identification of women with atrial fibrillation and appropriate management including anticoagulation of these women should be measured.</p> <p>Other suggested metrics include assessment of the program’s impact on the following:</p> <ul style="list-style-type: none"> • PCP awareness of stroke risk and presentation in women • Rate of PCP identification of women at high risk for stroke • Women’s understanding of their risk of stroke and of signs and symptoms of stroke • Women’s adherence to lifestyle modifications and pharmaceutical treatments aimed at reducing the risk of stroke • Health economics
Target Audience	<p>The focus of the program should be generating meaningful change among primary care providers (including internists, family practitioners, gynecologists, nurse practitioners, and physician assistants) and in women. Other healthcare providers may be targeted by the program, such as geriatricians, neurologists, cardiologists, and pharmacists.</p>
Geographic Scope:	<p><input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International (specify country/countries)_____</p> <p>.</p>
Applicant Eligibility Criteria:	<p>Medical, dental, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, for-profit health systems, professional associations and other not-for-profit entities may apply. Collaborations between organizations are encouraged.</p>
Expected Approximate Monetary Range of Grant Applications:	<p>Individual grants requesting up to \$1,000,000 will be considered. The total available budget related to this RFP is \$2,000,000.</p> <p>The amount of the grant Pfizer will be prepared to fund for any full proposal will depend upon Pfizer’s evaluation of the proposal and costs involved and will be clearly stated in the grant approval notification.</p>

<p>Key Dates:</p>	<p>RFP release date: 9/13/2012</p> <p>Letter of Intent due date: 10/16/2012</p> <p>(Please note you must be registered in the system to submit an LOI. Please attempt to complete this process at least one week prior to submission in order to avoid delays as all registrations must be approved before access to the system is granted).</p> <p>Anticipated LOI Notification Date: 11/16/2012</p> <p>Please note, full proposals can only be submitted following acceptance of an LOI Full Proposal Deadline: To be communicated on acceptance of an LOI.</p> <p>Anticipated Full Proposal Notification Date: To be communicated on acceptance of an LOI</p> <p>Anticipated award delivered following execution of fully signed LOA</p> <p>Period of Performance: 01/2013 to 01/2015</p> <p>Requirements for submission: If not already registered, register in the system to submit an LOI. Please attempt to complete this process <u>at least one week</u> prior to submission in order to avoid delays as all registrations must be approved before access to the system is granted. Complete all applicable sections of the online application and upload the completed LOI guidance template. Note that only certain sections/questions of the application are applicable to the Letter of Intent submission (see details in LOI guidance below).</p>
<p>How to Submit:</p>	<p>Submit LOIs online via the Pfizer Medical Education Group website www.pfizermededgrants.com Submit LOIs in the clinical area: LOI-RFP “Prevention of Stroke in Women”.</p>
<p>Questions:</p>	<p>If you have questions, please submit them in writing so that if appropriate Questions and Answers can be posted on the website. Send questions to MedEdGrants@Pfizer.com with the subject line “RFP “Prevention of Stroke in Women”. Other communications may also be directed to the Education Director for this clinical area, Robert E. Kristofco, via email robert.kristofco@pfizer.com</p>
<p>Mechanism by Which Applicants will be Notified:</p>	<p>All applicants will be notified via email. Providers may be asked for additional clarification or to make a summary presentation during the review period.</p>

References

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7. Tsadok MA, Jackevicius CA, Rahme E, et al. Sex differences in stroke risk among older patients with recently diagnosed atrial fibrillation. *JAMA* 2012;307(18):1952-1958.
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10. Mosca L, Benjamin EJ, Berra K, et al. Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women – 2011 Update. *Circulation* 2011;123:1243-1262.
11. Almdal T, Scharling H, Jensen JS, et al. The independent effect of Type 2 diabetes mellitus on ischemic heart disease, stroke, and death: a population-based study of 13,000 men and women with 20 years of follow-up. *Arch Intern Med* 2004;164(13):1422–1426.
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13. Mosca L, Linfante AH, Benjamin EJ, et al. National study of physician awareness and adherence to cardiovascular disease prevention guidelines. *Circulation* 2005;111(4):499–510.
14. Towfighi A, Saver JL, Engelhardt R, et al. A midlife stroke surge among women in the United States. *Neurology* 2007;69:1898–1904.

III. Terms and Conditions

1. Complete TERMS AND CONDITIONS for Certified and/or Independent Professional Healthcare Educational Activities are available upon submission of a grant application on the Medical Education Group website www.Pfizermededgrants.com.
2. This RFP does not commit Pfizer to award a grant, or to pay any costs incurred in the preparation of a response to this request.
3. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel in part or in its entirety this RFP, if it is in the best interest of Pfizer to do so.
4. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media.
5. For compliance reasons and in fairness to all providers, all communications about the RFP must come exclusively to the Medical Education Group. Failure to comply will automatically disqualify providers.
6. Pfizer reserves the right to share the title of your proposed project, and the name, address, telephone number and e-mail address of the requestor for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations).

IV. Transparency

Consistent with our commitment to openness and transparency, Pfizer reports education grants provided to medical, scientific and patient organizations in the United States. In the case of this RFP, a list of all LOIs selected to move forward may be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports etc) may be posted on the Pfizer MEG website.

Appendix: Letter of Intent Submission Guidance

LOIs should be single spaced using Calibri 12-point font and 1-inch margins. *Note that the main section of the LOI has a 3-page limit.*

LOIs will include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Goal

1. Briefly state the overall goal of the intervention

C. Objectives

1. List the *overall* objectives you plan to meet with your intervention both in terms of learning and expected outcomes. Do not include learner objectives.

D. Assessment of Need for the Intervention

1. Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in *your* target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. The RFP includes a national assessment of the need for the intervention. Please do not repeat this information within the LOI (you may reference the RFP if needed). Only include information that impacts your specific intervention, linking regional or local needs to those identified on the national basis if appropriate.

2. Describe the primary audience(s) targeted for this intervention. Also indicate who you believe will directly benefit from the project outcomes.

E. Intervention Design and Methods

1. Describe the planned intervention and the way it addresses the established need.

F. Design of Outcomes Evaluation

1. Describe how you will determine if the practice gap identified in the needs assessment was addressed for the target group in terms of the metrics used for the needs assessment.

- Identify the sources of data that you anticipate using to make the determination.
- Describe how you expect to collect and analyze the data.
- Explain the method used to control for other factors outside this intervention (e.g., use of a control group, comparison with baseline data)

- b. Quantify the amount of change expected from this intervention in terms of your target audience

c. Describe how you will determine if the target audience was fully engaged in the intervention.

d. Describe how the project outcomes might be broadly disseminated.

G. Preexisting Work

1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other programs or materials already developed. Describe how this initiative builds upon existing work, pilot projects, or ongoing programs, etc

H. Project Timeline

I. Requested Budget

J. Additional Information

1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please note it in within the page limitations

Organizational Detail (not to exceed 1 page):

Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed intervention.