Bristol-Myers Squibb/Pfizer Alliance Independent Medical Education/Global Medical Grants Request for Educational Support (RFE)

Date	March 27, 2019
RFE Requestor Information RFE Code	Name: Sylvia Nashed, PharmD, RPh Title: IME Specialist Phone: 609-302-3320 E-mail: Sylvia.nashed@bms.com RFE-19-CV-101
Therapeutic Area	Cardiovascular (CV)
Area of Interest	Undiagnosed Nonvalvular Atrial Fibrillation (NVAF) It is our intent to support Quality Improvement (QI) initiatives that focus on decreasing the number of people with undiagnosed/untreated NVAF (ie, diagnosed but not anticoagulated as per guidelines) within healthcare teams, especially those with increased risk factors, such as age ≥65 years, heart failure (left ventricular dysfunction), hypertension, diabetes, prior stroke or embolism, and vascular disease (peripheral vascular disease, prior MI, or aortic plaque). Of specific interest are QI initiatives that increase awareness of the burden and consequences of the undiagnosed/untreated NVAF (ie, diagnosed but not anticoagulated as per guidelines) population and provide tools to improve identification of undiagnosed NVAF and help reduce risk of preventable stroke. There is a considerable amount of interest in receiving responses from projects that address system-based changes within a health system/IDN/institution. A successful proposal should include: Clear and concise statement of the aims and expected outcomes for the project Specific plan of action for addressing areas of needed improvement Tools that provide learners the opportunity to facilitate change, individually and within their healthcare system Measurement consistent with project aims and expected outcomes

Educational Design	 A Quality Improvement educational collaborative implementing the cycle of:¹ Planning the strategy based on goals and identified objectives (inclusive of educational component) Implementing the components of the plan Studying and assessing the outcomes to evaluate progress and make needed plan changes Reflecting on the initiative and adjusting. This will lead to starting the process again with the planning component. The initiative should measure improvement of learners' knowledge, confidence, competency, and performance and achieve at least a Moore's Level 5 impact. Proposals with higher level outcomes (Moore's Level 5 and 6) will be given higher priority. Proposals with multi-collaborators will be given higher priority.
Intended Audience (may include, but not limited to)	Primary Care Providers, Cardiologists, Allied Healthcare Professionals (ie, NPs, PAs, pharmacists), payors, and/or other healthcare professionals involved in the care of patients with CV disease
Budget/Budget Range	The maximum amount of funding available for this RFE is \$400,000. Single or multi-supported initiatives will be considered.
Accreditation	ACCME, ANCC, ACPE, and others as appropriate
Geographic Coverage	United States
Deadline for Submission	May 7, 2019 by 5 PM EST

Background

Atrial fibrillation (AF) remains one of the major causes of stroke, heart failure, sudden death and cardiovascular morbidity in the world. Nonvalvular atrial fibrillation (NVAF) has been defined as atrial fibrillation in the absence of moderate-to-severe mitral stenosis or a mechanical heart valve.² According to a retrospective study of a large claims database including commercial health insurance and Medicare Advantage health plan, NVAF prevalence was projected to increase from 5.2 million cases in 2010 to 7.5 million cases in 2018.³ International studies from Sweden and Japan have demonstrated that 25%-38% of the AF population is undiagnosed.^{4,5} The prevalence of undiagnosed NVAF (and therefore lack of treatment and monitoring by a healthcare provider) is disturbing, as AF patients have 5-fold higher risk of developing a stroke and ~2-fold risk of dying from stroke.⁶ The attributable risk of stroke increases from 1.5% at 50 to 59 years of age to 23.5% at 80 to 89 years of age.⁷

Screening is important to help identify at risk patients appropriate for intervention/treatment; subsequent intervention/treatment of such patients may help reduce the risk of cardiovascular events, including helping prevent preventable strokes. The 2016 European Society of Cardiology (ESC) Guidelines for the management of atrial fibrillation includes the following two recommendations:⁸

- Opportunistic screening for AF is recommended by pulse taking or electrocardiogram rhythm strip in patients >65 years of age
- Systematic ECG may be considered for patients >75 years or those at high risk of stroke.

Literature reviews have summarized that there are two main approaches for AF screening:9

- Opportunistic screening during routine medical consultation.
- Systematic screening done in a wider range of people than those who present for routine medical consultations, including:
 - Targeted screening for those at higher risk for AF
 - o Population screening for a particular population not previously diagnosed with AF

With the proliferation of technology to assess heart rhythm, healthcare providers can assess patients' results easily with simple, non-invasive devices and including pulse palpation. Both opportunistic and systematic screenings are effective to identify new patients with NVAF at a similar rate. ¹⁰ In fact, one-time and multiple times or extended-screening AF studies have shown the percentage of AF patients who are newly diagnosed by screening ranges from 19% to 43%, and 25% respectively. ¹⁰⁻¹⁴ Screenings are also beneficial in that they may identify previously diagnosed yet untreated patients, as shown in the initial publication of the STROKESTOP study.

Education on the association between NVAF and increased stroke risk, importance and application of NVAF screening in practice, and subsequent treatment of patients diagnosed with NVAF can reduce the risk of stroke in these NVAF patients. A quality improvement initiative within a health system with a collaborative approach, via incorporation of various associations, societies, and medical education providers, will allow for a cost-effective means of reaching a broader audience and enhancing patient outcomes.

Educational Needs and Professional Practice Gaps:

BMS and Pfizer Alliance has identified, through insights from educational needs assessments, literature search, learning outcomes, and other methods, the need to address existing professional practice gaps by providing education around the importance of identifying and screening patients for NVAF, in an effort to reduce risk of strokes and thereby reduce stroke-related morbidity and mortality, and improve patient/patient-family outcomes. Previous experience and outcomes from CME activities have demonstrated that collaborative initiatives using a mix of live, social media and online educational modalities have significantly increased the engagement of interdisciplinary teams and the quality of care that they provide to their patients.

Through independent needs assessments, BMS and Pfizer Alliance has determined health care providers have the following educational needs and professional practice gaps:

- Need to better understand the implications of undiagnosed/untreated NVAF (diagnosed but not anticoagulated as per guidelines)—missed opportunities to prevent preventable strokes with potential result of stroke or systemic embolism)
- Need to become familiar with the different types of screenings for NVAF (including pulse palpation and available technique and devices), and be able to apply such screenings into routine clinical practice/system-based care
- Need to treat, follow-up and/or refer patients who are diagnosed with NVAF as appropriate

• Need to enhance networking and collaborations among healthcare providers to improve patient care, and potentially impact patients, families, and their communities.

Specific Area of Interest

The BMS Pfizer Alliance is seeking grant applications for development and implementation of a well-designed, innovative, interactive, and educational Quality Improvement collaborative that addresses the above educational needs and professional practice gaps. Based on a series of systematic reviews conducted by Dr. Cervero to assess the impact of CME, activities that are more interactive, apply multiple methods and multiple exposures, and are focused on outcomes that are considered important by physicians, lead to more positive outcomes. ¹⁵ A well-structured quality improvement program can have lasting impact on health systems that may improve patient outcomes. ¹⁶ Proposals that incorporate such findings into the design and development of the educational activity will be given higher priority.

The content and/or the format of the CME/CE activity and its related materials must be current and designed in such a way that it addresses the educational needs of the intended audiences as described in this RFE.

Grant Proposals should include, but not be limited to, the following information:

- Executive Summary: The Executive Summary should consist of 1-2 pages and highlight the key areas as described below.
- Needs Assessment/Gaps/Barriers: Needs assessment should be referenced and demonstrate
 an understanding of the specific gaps and barriers of the target audiences. The needs
 assessment must be independently developed and validated by the educational provider.
- Target Audience and Audience Generation: Target audience for educational program must be identified within the proposal. In addition, please describe methods for reaching target audience(s) and any unique recruitment methods that will be utilized. The anticipated or estimated participant reach should also be included, with a breakdown for each modality included in the proposal, as applicable (e.g., number of participants for the live activity, the live webcast, and enduring activity).
- <u>Learning Objectives:</u> The learning objectives must be written in terms of what the learner will achieve as a result of attending. The objectives must be clearly defined, measurable, and attainable and address the identified gaps and barriers.
- <u>Program Evaluation and Outcomes Reporting:</u> Description of the approach to evaluate the quality of the educational program. Describe methods used for determining the impact of the educational program on closing identified healthcare gaps.
 - Please refer to "Guidance for Outcomes Report" (on the BMS grants website) for a detailed explanation of preferred outcomes reporting methods and timelines.
 - Remember that knowledge, performance and competency based outcome measures according to Moore's Levels 4 & 5 are required. Level 6 outcomes are highly favored and recommended when possible.

- Educational Design and Methods: Describe the approach used to address knowledge, competence, and performance gaps that underlie identified healthcare gaps. The proposal should include strategies that ensure reinforcement of learning through use of multiple educational interventions and include practice resources and tools, as applicable.
- Communication and Publication Plan: Provide a description of how the provider will communicate the progress and outcomes of the educational program to the supporter. It is highly recommended to describe how the results of the activity will be presented, published, or disseminated.
- <u>Innovation</u>: Describe how this project is innovative and engages the learners to improve
 knowledge, competence and/or performance. Further describe how this project might build on
 existing work, pilot projects or ongoing projects developed either by your institution or other
 institutions related to this topic.
- <u>Budget:</u> Detailed budget with rationale of expenses, including breakdown of costs, content cost per activity, out-of-pocket cost per activity, and management cost per activity.

<u>Note:</u> The accredited provider and, if applicable, the medical education partner (MEP) or other third party executing the activities, are expected to comply with current ethical codes and regulations. They must have a conflict-of-interest policy in place to identify and resolve all conflicts of interest from all contributors and staff involved in developing the content of the activity prior to delivery of the program, and must have a separate company providing/accrediting independent medical education if they are also performing promotional activities.

If your organization wishes to submit an educational grant request, please use the online application available on the Bristol-Myers Squibb Independent Medical Education website.

http://www.bms.com/responsibility/grantsandgiving.

References:

- Section 4: Ways to approach the Quality Improvement process. Content last reviewed July 2017.
 Agency for Healthcare Research and Quality, Rockville, MD.
 http://www.ahrq.gov/cahps/quality-improvement/improvement-guide/4-approach-qi-process/index.html
- January, Craig T, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation. *Circulation*. 2019; doi:10.1161/cir.0000000000000665.
- Colilla S, Crow A, Petkun W, Singer DE, Simon T, Liu X. Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. *Am J Cardiol*. 2013;112(8):1142-7.
- 4. Friberg L, et al. Population screening of 75- and 76-year-old men and women for silent atrial fibrillation (STROKESTOP) *Europace*. 2013;15:135–40.
- 5. Honma K, Toyoda K, Takizawa S, et al. Abstract TP179: Atrial Fibrillation Unidentified Prior to Stroke/tia: Background Features, Stroke Severity and Outcome The Samurai-nvaf Study. *Stroke*. 2014;45:ATP179.
- 6. Lin HJ, Wolf PA, Kelly-Hayes M, Beiser AS, Kase CS, Benjamin EJ, et al. Stroke severity in atrial fibrillation. The Framingham study. *Stroke*. 1996;27:1760–4.

- 7. Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. *Stroke*. 1991;22(8):983-8.
- 8. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS: The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC Endorsed by the European Stroke Organisation (ESO). *Eur J Cardiothorac Surg*. 2016.
- 9. Moran PS, Flattery MJ, Teljeur C, Ryan M, Smith SM. Effectiveness of systematic screening for the detection of atrial fibrillation. *Cochrane Database Syst Rev.* 2013;(4):CD009586.
- Fitzmaurice DA, Hobbs FD, Jowett S, et al. Screening versus routine practice in detection of atrial fibrillation in patients aged 65 or over: cluster randomised controlled trial. *BMJ*. 2007;335(7616):383.
- 11. Hobbs FDR, Fitzmaurice DA, Mant J, et al. A randomised controlled trial and cost-effectiveness study of systematic screening (targeted and total population screening) versus routine practice for the detection of atrial fibrillation in people aged 65 and over. The SAFE study. Health Technol Assess 2005; 9 iii–iv, ix–x, 1–74.
- 12. Lowres N, Neubeck L, Redfern J, Freedman SB. Screening to identify unknown atrial fibrillation. A systematic review.. *Thromb Haemost*.. 2013; 110:213–222.
- 13. Lowres N, Neubeck L, Salkeld G, Krass I, McLachlan AJ, Redfern J, Bennett AA, Briffa T, Bauman A, Martinez C, Wallwnhorst C, Lau JK, Brieger DB, Sy RW, Freedman SB. Feasibility and cost-effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies. The SEARCH-AF study. *Thromb Haemost.* 2014;111:1167–1176.
- 14. Svennberg E, Engdahl J, Al-Khalili F, Friberg L, Frykman V, Rosenqvist M. Mass screening for untreated atrial fibrillation: the STROKESTOP Study. *Circulation*. 2015;131:2176–2184.
- 15. Cervero RM, Gaines JK. The impact of CME on physician performance and patient health outcomes: An updated synthesis of systematic reviews. *Journal of Continuing Education in the Health Professions*. 2015;35(2):131-138.
- 16. Nicolucci A, et al. Four-year impact of a continuous quality improvement effort implemented by a network of diabetes outpatient clinics: the AMD-Annals Initiative." *Diabetic Medicine*. 2010;27(9):1041-1048. doi:10.1111/j.1464-5491.2010.03055.x.