

Bristol Myers Squibb
Independent Medical Education
Request for Educational Support (RFE)

Date	May 21, 2024
RFE Requestor Information	Name: Mark Morgan, PharmD, RPh Title: Associate Director, Global Medical Education Phone: 908 812-2838 E-mail: Mark.Morgan@bms.com
RFE Code	RFE-24-HCM-101
Therapeutic Area	Cardiovascular
Area of Interest	<p>Implementation of Care Paths in oHCM to improve Guideline-Directed Medical Therapy</p> <p>It is our intent to support a multi-phased Quality Improvement (QI) initiative focused on:</p> <ul style="list-style-type: none"> • Improved adherence to guideline directed medical therapy (GDMT), including treatment modalities and real-world evidence • Improved standardization and treatment optimization of obstructive HCM (oHCM) to improve quality of care and align with patients’ interests • Improved coordination of care for multidisciplinary health care provider (HCP) teams treating/managing patients with oHCM <p>IMPORTANT: It is not the intent of this Request to support clinical research projects. Research projects, such as those evaluating therapeutic or diagnostic agents, will not be considered.</p>
Educational Design	<p>Multi-phased QI educational initiative focused on improved standardization of care pathways and coordination of care of oHCM patients. We are interested in receiving proposals from projects that address system-based changes within a health system/IDN/institution.</p> <ul style="list-style-type: none"> • The expectation is the QI initiative will be focused on activities that lead to measurable improvement in health care services and the health status of individuals and targeted patient groups and do not specifically relate to a BMS asset. • Quality improvement initiatives consider aspects of quality such as clinical competence, outcomes and process assessment, program evaluation, quality indicators, and quality assurance using

	<p>methodologically rigorous protocols with an endpoint goal of readiness for application to clinical practice</p> <ul style="list-style-type: none"> • Projects can be implemented within large and small hospitals, academic medical centers, community hospitals, ambulatory care settings, and other healthcare facilities, such as nursing homes • During review, the intended outcome of the project will be given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given high priority • Online resource tools and patient education journey and/or resources <p>A successful proposal should include:</p> <ul style="list-style-type: none"> • 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 <p>Proposals that include the following will be given higher priority:</p> <ul style="list-style-type: none"> • QI initiatives that utilize electronic medical records (EMRs) for assessment of outcomes (baseline and post-initiative) and are implemented in collaboration with academic congresses, societies, and/or institutions • Educational tools and resources that improve the care coordination among HCPs • Higher level outcomes (Moore’s Level 5 and 6)
Intended Audience (may include, but not limited to)	Cardiologists, Interventional Cardiologists, Electrophysiologists, and Cardiac Surgeons, Primary Care Practitioners (Physicians, NPs, PAs), and other HCPs who are part of the oHCM care team
Budget/Budget Range	The maximum amount of funding available for this RFE is \$400,000-\$500,000
Accreditation	ACCME and others as appropriate
Geographic Coverage	United States
Deadline for Submission	July 15, 2024 by 5 PM EST
Expected Program Launch	October 2024

Background

Hypertrophic Cardiomyopathy (HCM) is a disorder of the cardiac muscle that is conservatively estimated to affect as many as 20 million people worldwide.¹ In the United States, the incidence is projected to be around 750,000 Americans with the overwhelming majority of patients remaining undiagnosed (approximately 600,000 patients).^{1, 2} HCM is associated with serious adverse complications such as heart failure, arrhythmias, and stroke.³ Additionally, the mortality rate in patients with HCM has been shown to be approximately 3 times higher than the US general population at similar ages.³ While not common, the most feared complication is sudden cardiac death (SCD), which is estimated to affect approximately 0.5-1% of people diagnosed with HCM.⁴

HCM is a chronic, progressive disease of the cardiomyocyte that is characterized by unexplained left ventricle wall thickening.⁵ Cardiac myocyte abnormality in HCM is largely driven by sarcomeric dysfunction which leads to excessive myosin-actin cross-bridging.⁶ HCM can be a genetic disease with the most common mutation occurring in the sarcomere proteins.^{6, 7}

HCM has two main presentations of the disease; obstructive HCM and nonobstructive HCM.⁸ Current estimates are as high as up to 70% for obstructive HCM and up to 30% for nonobstructive HCM, but estimates can vary.^{5, 8} In patients with obstructive HCM, septal wall hypertrophy leads to left ventricular outflow tract obstruction (LVOTO) and can be accompanied by systolic anterior motion (SAM).^{5, 8} SAM of the mitral valve leaflets can also contribute to LVOTO.⁵ In nonobstructive HCM, hypertrophy of the cardiac muscle occurs without blood flow restriction due to obstruction.⁷

Recognition of HCM is challenging due to the heterogeneity of the disease and the commonality of the symptoms with relation to other cardiovascular diseases as well as non-cardiovascular diseases such as asthma or anxiety.^{9, 10} Most common symptoms of HCM include dyspnea (especially on exertion), fatigue, chest pain, palpitations, lightheadedness/dizziness, and syncope.^{5, 9} Current guidelines recommend that diagnosis of HCM include a clinical evaluation with symptomatology and family history, physical examination, EKG, and established with cardiac imaging.^{5, 7} Genetic screening of family members can also help with the identification of people at risk of HCM.¹¹

Echocardiography is the primary modality of cardiac imaging used for establishing a diagnosis of HCM.² An integral part of echocardiography in the diagnosis of HCM is characterization of the LVOTO.¹² However, due to the dynamic nature of LVOTO, guidelines recommend echocardiography with provocation (e.g. Valsalva maneuver, exercise stress, and post-prandial upright exercise) may be better techniques than echocardiography at rest to confirm obstruction.^{5, 7} Additionally, if HCM is suspected and echocardiography is inconclusive, additional imaging such as cardiovascular magnetic resonance can be used for diagnosis.¹³

Historical pharmacological therapies that have been available provided symptomatic relief and have been delivered on an empirical basis.⁵ In obstructive HCM, non-vasodilating beta-blockers are generally considered first line with alternative agents being the non-dihydropyridine (non-DHP) calcium channel blockers.^{5, 14, 16} Similarly in nonobstructive HCM, beta-blockers and calcium channel blockers are first line, despite limited and low-level evidence.⁵ The updated 2024 guidelines state, "For patients who do not respond to trials of ≥ 1 of these drugs, advanced therapies with disopyramide, cardiac myosin inhibitors, or septal reduction are often the next step."¹⁶

Educating an multidisciplinary audience on the pathophysiology of HCM, diagnostic strategies, current Guidelines recommendations, and the significant unmet needs for patients will help develop competence in managing HCM, reduce under- and misdiagnosis, and potentially improve the quality of care and align with patients' interests.

Educational Needs and Professional Practice Gaps:

BMS has identified, through insights from educational needs assessments, literature search, learning outcomes, and other methods, the need to address the following existing professional practice gaps by providing education on appropriate management of HCM the need of:

- Educate on the prevalence, pathophysiology, unmet patient needs, and consequences of oHCM
- Better understand the implications of undiagnosed oHCM and improve HCPs management
- Understand and integrate into clinical practice care paths the current, evidence-based guidelines in managing oHCM, as they evolve and new data becomes available
- Treat, follow-up and/or refer patients who are diagnosed with oHCM as appropriate
- Enhance networking and care coordination among healthcare providers to improve patient care, following guideline and expert opinion recommendations for the management of oHCM

The activity(ies) will ensure timely and effective communication of the latest science, clinical trial data, and evidence-based guidelines for the management of oHCM patients. Key clinical data, barriers to care, and practice gaps will be addressed through the educational program.

Specific Area of Interest

BMS is seeking grant applications for development and implementation of a well-designed, innovative, interactive, and educational program 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.¹⁷ 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 through triangulation.

- **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).
- **Learning Objectives:** 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, attainable, and address the identified gaps and barriers.
- **Program Evaluation and Outcomes Reporting:** 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.
- **Innovation:** 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.
- **Budget:** 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.

Note: 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:

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