for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for treatment strategies for patients with peripheral artery disease (PAD).

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on treatment strategies for patients with peripheral artery disease, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-GUIDESreviews-and-reports/?PAGEaction=displayproduct&productid=948#4546.*

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.*

The Key Questions

KQ 1: In adults with peripheral artery disease (PAD), including asymptomatic patients and symptomatic patients with atypical leg symptoms, intermittent claudication (IC), or critical limb ischemia (CLI):

a. What is the comparative effectiveness of aspirin and other antiplatelet agents in reducing the risk of adverse cardiovascular events (e.g., all-cause mortality, myocardial infarction, stroke, cardiovascular death), functional capacity, and quality of life?

b. Does the effectiveness of treatments vary according to the patient's PAD classification or by subgroup (age, sex, race, risk factors, or comorbidities)?

c. What are the significant safety concerns associated with each treatment strategy (e.g., adverse drug reactions, bleeding)? Do the safety concerns vary by subgroup (age, sex, race, risk factors, comorbidities, or PAD classification)?

KQ2: In adults with symptomatic PAD (atypical leg symptoms or IC): a. What is the comparative effectiveness of exercise training, medications (cilostazol, pentoxifylline), endovascular intervention (percutaneous transluminal angioplasty, atherectomy, or stents), and/or surgical revascularization (endarterectomy, bypass surgery) on outcomes including vessel patency, repeat revascularization, wound healing, analog pain scale score, cardiovascular events (e.g., all-cause mortality, myocardial infarction, stroke, cardiovascular death), amputation, functional capacity, and quality of life?

b. Does the effectiveness of treatments vary by use of exercise and medical therapy prior to invasive management or by subgroup (age, sex, race, risk factors, comorbidities, or anatomic location of disease)?

c. What are the significant safety concerns associated with each treatment strategy (e.g., adverse drug reactions, bleeding, contrast nephropathy, radiation, infection, exercise-related harms, and periprocedural complications causing acute limb ischemia)? Do the safety concerns vary by subgroup (age, sex, race, risk factors, comorbidities, anatomic location of disease)?

KQ3: In adults with CLI due to PAD:

a. What is the comparative effectiveness of endovascular intervention (percutaneous transluminal angioplasty, atherectomy, or stents) and surgical revascularization (endarterectomy, bypass surgery) for outcomes including vessel patency, repeat revascularization, wound healing, analog pain scale score, cardiovascular events (e.g., all-cause mortality, myocardial infarction, stroke, cardiovascular death), amputation, functional capacity, and quality of life?

b. Does the effectiveness of treatments vary by subgroup (age, sex, race, risk factors, comorbidities, or anatomic location of disease)?

c. What are the significant safety concerns associated with each treatment strategy (e.g., adverse drug reactions, bleeding, contrast nephropathy, radiation, infection, and periprocedural complications causing acute limb ischemia)? Do the safety concerns vary by subgroup (age, sex, race, risk factors, comorbidities, or anatomic location of disease)?

Dated: February 15, 2012.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2012–4261 Filed 2–23–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Treatment of Atrial Fibrillation

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of atrial fibrillation medical devices. Scientific information is being solicited to inform our Comparative Effectiveness Review of the Treatment of Atrial Fibrillation, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program.

Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173.

DATES: Submission Deadline on or before March 26, 2012.

ADDRESSES: *Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submitscientific-information-packets/.* Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

Email submissions: ehcsrc@ohsu.edu (please do not send zipped files—they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239–3098.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–494–0147 or Email: *ehcsrc@ohsu.edu.*

SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for the treatment of atrial fibrillation.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on atrial fibrillation treatment, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://effectivehealthcare.AHRQ.gov/index.cfm/search-for-GUIDES-reviewsandreports/?PAGEaction=displayproduct&productid=946.*

This notice is a request for industry stakeholders to submit the following:

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The Key Questions

Our first three KQs focus on rate-control therapies. Specifically:

KQ 1: What are the comparative safety and effectiveness of pharmacological agents used for ventricular rate control in patients with AF? Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?

KQ 2: What are the comparative safety and effectiveness of a strict rate-control strategy versus a more lenient rate-control strategy in patients with AF? Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?

KQ 3: What are the comparative safety and effectiveness of newer procedural and other nonpharmacological rate-control therapies compared with pharmacological agents in patients with AF who have failed initial pharmacotherapy? Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?

Our next three KQs focus specifically on rhythm-control therapies:

KQ 4: What are the comparative safety and effectiveness of available antiarrhythmic agents and electrical cardioversion for conversion of AF to sinus rhythm? Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?

KQ 5: What are the comparative safety and effectiveness of newer procedural rhythm-control therapies, other nonpharmacological rhythm-control therapies, and pharmacological agents (either separately or in combination with each other) for maintenance of sinus rhythm in patients with AF? Do the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?

KQ 6: What are the comparative diagnostic accuracy, diagnostic thinking, therapeutic, and patient outcome efficacy of echocardiographic studies and other clinical parameters for predicting successful conversion, successful ablation, successful maintenance of sinus rhythm, and improved outcomes in patients with AF?

Our final KQ seeks to evaluate the comparison of the available rate- and rhythm-control therapies.

KQ 7: What are the comparative safety and effectiveness of rhythm-control therapies compared to rate-control therapies in patients with AF? Does the comparative safety and effectiveness of these therapies differ among specific patient subgroups of interest?

Dated: February 15, 2012.

Carolyn M. Clancy,

Director, AHRQ.

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