

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Healthcare Research and Quality****Scientific Information Request on Treatment Strategies for Patients With Lower Extremity Chronic Venous Disease (LECVD)**

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 the public. Scientific information is being solicited to inform our review of *Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease (LECVD)*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Programs. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before July 11, 2016.

ADDRESSES:

Email submissions: SIPS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, Attn: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, Attn: Scientific Information Packet Coordinator, 3710 SW. U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SIPS@epc-src.org.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence for *Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease (LECVD)*. The EPC 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 requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease (LECVD)*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: http://www.AHRQ.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/lecvd_protocol.pdf.

This notice is to notify the public that the EPC Program would find the following information on *Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease (LECVD)* helpful:

□ A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

□ *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including 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 follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

□ *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

□ Description of whether the above studies constitute all Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC 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: https://subscriptions.ahrq.gov/accounts/USAHRQ/subscriber/new?topic_id=USAHRQ_18.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is available online at: http://www.AHRQ.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/lecvd_protocol.pdf.

KQ 1: Narrative review of the diagnostic methods and diagnostic criteria for all adult patients (symptomatic and asymptomatic) with LE varicose veins, LE chronic venous insufficiency/incompetence/reflux, and/or LE chronic venous thrombosis/obstruction (including post-thrombotic syndrome).

KQ 2: Regarding treatments for all adult patients (symptomatic and asymptomatic) with LE varicose veins and/or LE chronic venous insufficiency/incompetence/reflux:

I. What is the comparative effectiveness of exercise, medical therapy, weight reduction, mechanical compression therapy, and invasive procedures (i.e., surgical and endovascular procedures) on health outcomes?

II. What diagnostic method(s) and criteria were used in each study?

III. How does the comparative effectiveness of treatment vary by patient characteristics, including age, sex, risk factors, comorbidities, characteristics of disease, anatomic segment affected, and characteristics of the therapy (e.g., exercise intensity, type of mechanical compression)?

IV. What are the comparative safety concerns associated with each treatment strategy (e.g., adverse drug reactions, bleeding)? Do the safety concerns vary by patient subgroup (age, sex, race, risk factors, comorbidities, anatomic segment, or disease severity)?

KQ 3: Regarding treatments for all adult patients (symptomatic and asymptomatic) with LE chronic venous thrombosis/obstruction (including post-thrombotic syndrome):

I. What is the comparative effectiveness of exercise, medical therapy, mechanical compression therapy, and invasive procedures (i.e., surgical and endovascular procedures) on health outcomes?

II. What diagnostic method(s) and criteria were used in each study?

III. How does the comparative effectiveness of treatment vary by patient characteristics, including age, sex, risk factors, comorbidities, characteristics of disease, anatomic segment affected, and characteristics of the therapy (e.g., exercise intensity, type of mechanical compression)?

IV. What are the comparative safety concerns associated with each treatment strategy (e.g., adverse drug reactions, bleeding)? Do the safety concerns vary by patient subgroup (age, sex, race, risk factors, comorbidities, anatomic segment, or disease severity)?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

KQ 1: Diagnosis

I. Population(s):

- A. Adults (over age 18) with the diagnosis of LE varicose veins, LE chronic venous insufficiency/incompetence/reflux, and/or LE chronic venous thrombosis/obstruction (including post-thrombotic syndrome)

II. Diagnostic Measures:

- A. Air plethysmography, LE venous duplex ultrasonography (with and without compression), invasive venography, magnetic resonance venography, computed tomographic venography, serum D-dimer testing, Villalta score

III. Comparators:

- A. Diagnostic modalities listed above (air plethysmography, LE duplex venous ultrasonography [with and without compression], invasive venography, magnetic resonance venography, computed tomographic venography, serum D-dimer testing, Villalta score) will be compared to one another

IV. Outcomes:

- A. Sensitivity, specificity, positive predictive value, negative predictive value, inter-rater reliability, internal consistency, test-retest reliability, false positives, false negatives, and positive and negative likelihood ratios for each diagnostic measure listed above will be compared

V. Timing:

- A. Not applicable

VI. Settings:

- A. All clinical settings, including inpatient and outpatient

KQs 2–3: Treatment

I. Population(s):

- A. KQ 2: A symptomatic or symptomatic adults (over age 18) with the diagnosis of LE varicose veins and/or LE chronic venous insufficiency/incompetence/reflux:

- i. Subgroup analysis: age, race/ethnicity, sex, body weight, CEAP classification, VCSS classification, severity of disease, anatomic segment affected (e.g., iliofemoral, infrainguinal), known malignancy, presence of LE ulcer

- A. KQ 3: A symptomatic or symptomatic adults (over age 18) with the diagnosis of LE chronic venous thrombosis/obstruction (including post-thrombotic syndrome):

- i. Subgroup analysis: age, race/ethnicity, sex, body weight, CEAP classification, VCSS classification, Villalta score, severity of disease, anatomic segment affected (e.g., iliofemoral, infrainguinal), known malignancy, presence of LE ulcer

II. Interventions:

- A. KQ 2: lifestyle interventions (e.g., smoking cessation, leg elevation, weight reduction, exercise), medical therapy, local skin care/wound care, mechanical compression therapy, and invasive procedures (i.e., surgical and endovascular procedures)

- i. Medical therapies: diuretics, aspirin, pentoxifylline, prostacyclins, zinc sulfate
- ii. Invasive surgical/endovascular procedures: sclerotherapy (liquid, foam, glue), radiofrequency ablation, thermal ablation, chemical ablation, ambulatory phlebectomy, transilluminated powered phlebectomy, venous ligation, venous excision

- B. KQ 3: lifestyle interventions (e.g., smoking cessation, leg elevation, weight reduction, exercise), medical therapy, local skin care/wound care, mechanical compression therapy, and invasive procedures (i.e., surgical and endovascular procedures)

- i. Medical therapies: anticoagulants including warfarin, apixaban, rivaroxaban, edoxaban, and dabigatran; diuretics
- ii. Invasive surgical/endovascular procedures: endovenous angioplasty/stenting, ultrasound accelerated thrombolysis for chronic DVT (EkoSonic® endovascular system), surgical thromboembolectomy

III. Comparators:

- A. Specific treatments will be compared to other included treatments as described above or to no treatment (placebo or usual care)

IV. Outcomes:

- A. Changes on standardized symptom scores (Villalta score, CEAP classification, AVVQ score, and VCSS score); qualitative reduction

in Ledema; qualitative reduction in LE pain; improvement in LE venous hemodynamics/reflux severity as measured by air plethysmography, duplex ultrasonography, or invasive venography; venous wound healing, recurrent ulceration, patient-reported quality of life (including AVVQ), repeat intervention, LE amputation E

- B. Adverse effects of treatment, including: adverse drug reactions; bleeding (including intracranial bleeding); venous wound infection; contrast nephropathy; radiation-related injuries; exercise-related harms; periprocedural complications (vessel dissection, vessel perforation, and AV fistula), thrombophlebitis, venous thrombosis (including stent thrombosis), venous thromboembolic events (including PE), and death

V. Timing:

- A. Studies with all durations of followup will be included in the review; for symptomatic patients, we will attempt to categorize studies into those that evaluate short-term (≤ 30 days), intermediate-term (31 days to 6 months), and long-term (≥ 6 months) events.

VI. Settings:

- A. Any

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2016–13761 Filed 6–9–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: “*Survey of Hospital Quality Leaders*.” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on February 10, 2016 and