

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 May 25, 2012.

ADDRESSES:

Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-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 chronic venous ulcer treatment modalities.

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 chronic venous ulcer treatments, 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-guides-reviews-and-reports/>

?productid=995&pageaction=displayproduct#4886

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

Question 1

For patients with chronic venous leg ulcers, what are the benefits and harms of using dressings that regulate wound moisture with or without active chemical, enzymatic, biologic, or antimicrobial components in conjunction with compression systems when compared with using solely compression systems?

Question 2

a. For patients with chronic venous leg ulcers that do not have clinical signs of cellulitis that are being treated with compression systems, what are the benefits and harms of using systemic antibiotics when compared with using solely compression systems?

b. For patients with chronic venous leg ulcers that do not have clinical signs of cellulitis that are being treated with dressings that regulate wound moisture with or without active chemical, enzymatic, biologic, or antimicrobial components, what are the benefits and harms of using systemic antibiotics when compared with using dressings alone?

Question 3

a. For patients with chronic venous leg ulcers, what are the benefits and harms of surgical procedures aimed at the underlying venous abnormalities when compared with using solely compression systems?

b. For patients with chronic venous leg ulcers, what are the comparative benefits and harms of different surgical procedures for a given type of venous reflux and obstruction?

Dated: April 12, 2012.

Carolyn M. Clancy,
AHRQ, Director.

[FR Doc. 2012–9820 Filed 4–24–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Secondary Review

The meeting announced below concerns Grants for Injury Control Research Centers, Funding Opportunity Announcement (FOA) CE12–001, secondary review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned SEP:

Time and Date: 1 p.m.–3 p.m., May 31, 2012 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the secondary review and discussion

of competitive applications following initial review of applications received in response to "FOA CE12-001, Grants for Injury Control Research Centers (R49)."

Contact Person for More Information:

Christine Morrison, Ph.D., Director, Extramural Research Program Office, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE., Mailstop F63, Atlanta, Georgia 30341-3724, Telephone (770) 488-4233.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 18, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012-9935 Filed 4-24-12; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ATSDR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Times and Dates: 8:30 a.m.-4:30 p.m., May 17, 2012. 8:30 a.m.-12:15 p.m., May 18, 2012.
Place: CDC, 4770 Buford Highway, Atlanta, Georgia 30341.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC and Administrator, NCEH/ATSDR, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist states and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and well being; and (3) train state and local personnel in health

work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency's mission to protect and promote people's health. The board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Matters to be Discussed: The agenda items for the BSC Meeting on May 17-18, 2012 will include NCEH/ATSDR Office of the Director updates: ATSDR and NCEH Reorganization; update on the Nutritional Biomarker Report: Transfat analysis; ATSDR Science Symposium recommendations; presentation on Environmental Health Exposure Investigations; update on the Advisory Committee on Childhood Lead Poisoning Prevention; and updates by the BSC Federal Experts.

Agenda items are subject to change as priorities dictate.

Supplementary Information: The public comment period is scheduled on Thursday, May 17, 2012 from 3 p.m. until 3:15 p.m., and Friday, May 18, 2012 from 10:45 a.m. until 11 a.m.

Contact Person for More Information: Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, 4770 Buford Highway, Mail Stop F-61, Chamblee, Georgia 30345; telephone (770) 488-0575, Fax: (770) 488-3377; email: smalcom@cdc.gov. The deadline for notification of attendance is May 11, 2012.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 18, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012-9925 Filed 4-24-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Conducting Operational Research to Measure or Mitigate Morbidity and Mortality of Populations Affected by Humanitarian Emergencies,

Funding Opportunity Announcement (FOA) GH12-007, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

DATES: Time and Date: 1 p.m.-4 p.m., June 20, 2012 (Closed).

PLACE: Teleconference.

STATUS: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

MATTERS TO BE DISCUSSED: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Conducting Operational Research to Measure or Mitigate Morbidity and Mortality of Populations Affected by Humanitarian Emergencies, FOA GH12-007."

CONTACT PERSON FOR MORE INFORMATION: Diana Bartlett, Scientific Review Officer, Office of the Associate Director for Science, Office of Science Quality, CDC, 1600 Clifton Road NE., Mailstop D-72, Atlanta, Georgia 30033, Telephone (404) 639-4938.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 25, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012-9924 Filed 4-24-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0827]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma

AGENCY: Food and Drug Administration, HHS.