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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

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 Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), 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 Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 to upload your documents.
E-mail submissions:SIPS@epc-src.org.

Print submissions

Mailing Address:
Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
PO Box 69539
Portland, OR 97239

Shipping Address (FedEx, UPS, etc.):
Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
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Portland, OR 97239

FOR FURTHER INFORMATION CONTACT:
Ryan McKenna,Telephone: 503-220-8262 ext. 58653 or Email: SIPS@epcsrc.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).

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 requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1906#8766

This notice is to notify the public that the EHC program would find the following information on Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).

• A list of completed studies your company has sponsored for this indication. In the list, 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, 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 your company 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 company for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the 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 Effective Health Care 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 EHC program website 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 e-mail list at: http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.

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 also available online at: http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID= 1906#8766

Key Questions (KQs)

1. What methods are available to clinicians to diagnose ME/CFS and how do the use of these methods vary by patient subgroups?

A. What are widely accepted diagnostic methods and what conditions are required to be ruled out or excluded before assigning a diagnosis of ME/CFS?

B. What is the accuracy and concordance of diagnostic methods?

C. What harms are associated with diagnosing ME/CFS?

2. What are the (a) benefits and (b) harms of therapeutic interventions for patients with ME/CFS and how do they vary by patient subgroups?

A. What are the characteristics of responders and non-responders to interventions?

PICOTS (Population, Intervention, Comparator(s), Outcomes, Timing, Setting)

Population(s)

1. Include:

A. For KQ 1: Symptomatic adults (aged 18 years or older) with fatigue

B. For KQ 2: Adults aged 18 years or older, with ME/CFS, without other underlying diagnosis

2. Exclude:

A. Children and adolescents

B. Patients with other underlying diagnosis

Interventions

1. Include:

A. For KQ1: Case definitions: e.g., Fukada/CDC, Canadian, International and others

For KQ2: symptom-based medication management (immune modulators, beta blockers, antidepressants, anxiolytics, stimulants), forms of counseling and behavior therapy, graded exercise programs, complementary and alternative medicine (acupuncture, relaxation, massage, or other), and transcutaneous electrical nerve stimulation.

Comparators

1. Include:

A. For KQ1: Diagnostic accuracy studies and diagnostic concordance studies with comparators

B. For KQ2: Placebo or no treatment/usual care, other active interventions (including combination therapies and head-to-head trials)

Outcomes

1. Include:

A. For KQ1: Sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, C statistic (AUROC), net reclassification index; concordance, any potential harm from diagnosis (such as psychological harms, labeling, risk from diagnostic test, misdiagnosis, other)

B. For KQ2: Overall function (i.e., 36-item Short Form Survey [SF-36]), quality of life, days spent at work/school, proportion working full or part time, fatigue (Multidimensional Fatigue Inventory [MFI] or similar), adverse effects of interventions, withdrawals and withdrawals due to adverse events, rates of adverse events due to interventions

Timing

1. Include: 12 weeks or longer

Setting

1. Include: Clinical settings

Dated: June 3, 2014.

Richard Kronick,
AHRQ Director.

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