EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	51	4.25	[a] 53.69	$228
Program Information Form	51	4.25	[a] 53.69	228
Data Use Agreement	51	2.5	[b] 94.25	236
Data Files Submission	13	52	[c] 42.08	2,188
Total	** 166	63	NA	2,880

* National Compensation Survey: Occupational wages in the United States May 2017, ''U.S. Department of Labor, Bureau of Labor Statistics.''
[a] Based on the mean hourly wage for Medical and Health Services Managers (11–9111).
[b] Based on the mean hourly wage for Chief Executives (11–1011).
[c] Based on the mean hourly wages for Computer Programmer (15–1131).
** The 51 POCs listed for the registration form, program information form and the data use agreement are the estimated POCs from the estimated participating programs.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Gopal Khanna,

Director.

[FR Doc. 2019–05141 Filed 3–18–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Noninvasive Nonpharmacologic Treatment for Chronic Pain

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

ACTION: Request for supplemental evidence and data 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 on *Noninvasive Nonpharmacologic Treatment for Chronic Pain,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before April 18, 2019.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Noninvasive Nonpharmacologic Treatment for Chronic Pain.* AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

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 *Noninvasive Nonpharmacologic Treatment for Chronic Pain,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/topics/noninvasive-nonpharm-pain-update/protocol.*

This is to notify the public that the EPC Program would find the following information on Noninvasive Nonpharmacologic Treatment for Chronic Pain 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. Materials submitted must be publicly available or able to 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 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 email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

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 Key Questions

1. In adults with chronic low back pain:

a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?

b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy (*e.g.,* NSAIDS, acetaminophen, antiseizure medications, antidepressants)?

c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with exercise?

2. In adults with chronic neck pain:

a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?

b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy?

c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with exercise?

3. In adults with osteoarthritis-related pain:

a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?

b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy?

c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with exercise?

4. In adults with fibromyalgia:

a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?

b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy?

c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with exercise?

5. In adults with chronic tension headache:

a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?

b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy?

c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with biofeedback?

6. Do estimates of benefits and harms differ by age, sex, presence of comorbidities (*e.g.,* emotional or mood disorders) or degree of nociplasticity/central sensitization?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

- *Population(s):* Adults (including pregnant or breastfeeding women) with the following chronic pain (defined as pain lasting 12 weeks or longer or pain persisting past the time for normal tissue healing) conditions specified in the Key Questions:
  - *Key Question 1:* Nonradicular chronic low back pain.
  - *Key Question 2:* Chronic neck pain without radiculopathy or myelopathy.
  - *Key Question 3:* Pain related to primary or secondary osteoarthritis.
  - *Key Question 4:* Fibromyalgia.
  - *Key Question 5:* Primary chronic tension headache (defined as 15 or more headache days per month for at least 3 months).
  - *Key Question 6:* Patients with any of the five chronic pain conditions.
- *Interventions (All Key Questions):*
  - Exercise.
  - Psychological therapies.
  - Physical modalities.
  - Manual therapies.
  - Mindfulness practices.
  - Mind-body practices.
  - Acupuncture.
  - Multidisciplinary/interdisciplinary rehabilitation (including functional restoration training).
- *Comparators:*
  - For all Key Questions, subquestion ''a''.
    - Sham treatment.
    - Waitlist.
    - Usual care.
    - Attention control.
    - No treatment.
  - For all Key Questions, subquestion ''b''.
    - Common nonopioid pharmacologic therapy used for chronic pain (NSAIDs, acetaminophen, antiseizure medications, antidepressants, muscle relaxants (including benzodiazepines) topical agents,(diclofenac, lidocaine capsaicin).
    - Medical marijuana (any formulation).
    - Opioid analgesics.
  - Key Questions 1–4, 6, subquestion ''c'': Exercise.
  - Key Question 5, 6, subquestion ''c'': Biofeedback.
- *Outcomes:*
  - Primary efficacy outcomes (in priority order); we will focus on outcomes from validated measures.
    - Function/disability/pain interference.
    - Pain.
  - Harms and adverse effects.
  - Secondary outcomes.
    - Psychological distress (including depression and anxiety).
    - Quality of life.
    - Opioid use.
    - Sleep quality, sleep disturbance.
    - Health care utilization.
- *Timing:*
  - Duration of followup: short term (up to 6 months), intermediate term (6–12 months) and long term (at least 1 year); we will focus on longer-term (≤1 year) effects where possible.
  - Studies with <1 month followup after treatment will be excluded.
- *Settings:*
  - Any nonhospital setting or setting of self-directed care.
  - Exclusions: Hospital care, hospice care, emergency department care.

Gopal Khanna,

Director.

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