DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Living Systematic Review on Plant-Based 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 *Living Systematic Review on Plant-Based 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 January 4, 2021.

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 a *Living Systematic Review on Plant-Based Treatment for Chronic Pain.* AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

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 *Plant-Based Treatment for Chronic Pain,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/plant-based-chronic-pain-treatment/protocol.*

This is to notify the public that the EPC Program would find the following information on Plant-Based 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,* 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 is very beneficial to the 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.

Key Questions (KQs)

1. In adults with chronic pain, what are the benefits of cannabinoids?

2. In adults with chronic pain, what are the harms of cannabinoids?

3. In adults with chronic pain, what are the benefits of kratom or other plant-based substances for treatment of chronic pain?

4. In adults with chronic pain, what are the harms of kratom or other plant-based substances for treatment of chronic pain?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)

PICOTS element	Inclusion criteria	Exclusion criteria
Population	*All KQs:* Adults (including pregnant or breastfeeding women) 18 years and older with chronic pain (≤12 weeks or pain persisting past the time for normal tissue healing). See categorization of specifically included pain populations below.	*All KQs:* Children and adolescents <18 years old; adults with acute or subacute pain; patients at end of life or in palliative care (*e.g.,* with late stage cancer-related pain).
Interventions	*KQs 1 and 2:* Cannabinoids (including synthetics) using different delivery mechanisms such as oral, buccal, inhalational, topical, or other administration routes. *KQs 3 and 4:* Kratom or other plant-based substances; co-use of kratom or other plant-based substances and opioids. *All KQs:* Co-use of other drugs for pain.	*All KQs:* Non-plant-based interventions, capsaicin, herbal supplements.
Comparators	*All KQs:* Any comparator, or usual care	*All KQs:* No comparison.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

PICOTS element	Inclusion criteria	Exclusion criteria
Outcomes	*All KQs:* Primary efficacy outcomes (*i.e.,* pain, function, disability, pain interference); harms and adverse effects (*e.g.,* dizziness, nausea, sedation, development of cannabis use disorder); secondary outcomes (*i.e.,* psychological distress including depression and anxiety, quality of life, opioid use, sleep quality, sleep disturbance, health care utilization).	*All KQs:* Other outcomes.
Time of follow-up	*All KQs:* short term (1 to <6 months), intermediate term (6 to <12 months), long term (≥1 year).	*All KQs:* studies with <1-month of treatment or followup after treatment.
Setting	*All KQs:* Any nonhospital setting or setting of self-directed care.	*All KQs:* Hospital care, hospice care, emergency department care.
Study design	*All KQs:* RCTs; observational studies with a concurrent control group for harms, and to fill gaps in the evidence for benefits.	*All KQs:* Other study designs.

Abbreviations: RCT = randomized controlled trial.

Dated: November 27, 2020.

Marquita Cullom,

Associate Director.

[FR Doc. 2020–26570 Filed 12–1–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)-RFA–PS–21–003, PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices; and RFA–PS–21–004, Implementing and Evaluating a Data-to-Care Rx Strategy.

Date: February 23–24, 2021.

Time: 10:00 a.m.–5:00 p.m., EST.

Place: Teleconference, Centers for Disease Control and Prevention, Room 1080, 8 Corporate Square Boulevard, Atlanta, Georgia 30329–4027.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop US8–1, Atlanta, Georgia 30329–4027, (404) 718–8833, *GAnderson@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–26558 Filed 12–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2020–0121]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. The meeting will be webcast live via the World Wide Web.

DATES: The meeting will be held on December 1, 2020 from 2:00 p.m. to 5:00 p.m., EST (times subject to change).

Written comments must be received on or before December 3, 2020.

ADDRESSES: For more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

You may submit comments, identified by Docket No. CDC–2020–0121 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket No. CDC–2020–0121, c/o Attn: November 23, 2020 ACIP Meeting, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, GA 30329–4027.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is