SUPPLEMENTARY INFORMATION: The notice document submitted by Commission staff for publication contained a typographical error; specifically, the expiration date for the current OMB clearance was off by one year in the SUMMARY.

Correction

In notice FR Doc. 2024–25559 appearing at 89 FR 87575 in the **Federal Register** of Monday, November 4, 2024, make the following correction. On page 87576, in the last sentence of the **SUMMARY** section, the date of ''January 30, 2024'' is corrected to read ''January 31, 2025''.

Dated: November 20, 2024.

April J. Tabor,

Secretary.

[FR Doc. 2024–27794 Filed 11–26–24; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events

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

ACTION: Request for supplemental evidence and data submission.

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 *Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 December 27, 2024.

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: Kelly Carper, Telephone: 301–427–1656 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 *Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events.* AHRQ is conducting this 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 *Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/polyunsaturated-fatty/protocol.*

This is to notify the public that the EPC Program would find the following information on *Dietary Intake of Polyunsaturated Fatty Acids and Plasma Lipid and Cardiovascular Events* helpful:

- A list of completed studies that your organization has sponsored for this topic. 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, if relevant: 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 topic.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including, if relevant, 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 topic 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 topics 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://effectivehealthcare.ahrq.gov/email-updates.*

The 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 (KQ)

KQ 1: What are the effects of different dietary polyunsaturated fatty acid intake on plasma lipid concentrations in the general population?

KQ 2: What are the effects of different dietary polyunsaturated fatty acid intake on cardiovascular events in the general population?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

[Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
Population	*Both Key Questions:*	*Both Key Questions:*

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

[Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
	General population, without CVD, with or without modifiable CV risk factors, including ○ Dyslipidemia (including if taking lipid-lowering medications) ○ Overweight/obese ○ Hyperglycemia and related conditions, including type 2 diabetes ○ Hypertension/high blood pressure *Key Question 1:* Children and adults *Key Question 2:* Adults (≥18 years old)	• Participants with a health-related condition or taking medications that impact fat absorption, fat metabolism. • Participants taking weight loss medications, including glucagon-like peptide-1 agonists. • Undernourished, underweight, stunted, or wasted participants. • Participants who are pre- or post-bariatric surgery. • Participants with other chronic diseases (*e.g.,* cancer, gastrointestinal disease, rheumatic disease, chronic kidney disease, neurologic diseases), including type 1 diabetes. • Participants with clinical CVD (*e.g.,* history of myocardial infarction, angina, stroke, arrhythmia), including congenital heart diseases, or familial hypercholesterolemia.
Interventions	*Both Key Questions:* Dietary intake of Total n-3 or total n-6 PUFA Individual PUFA (*e.g.,* linoleic, ALA, EPA, DHA) Combination of long-chain PUFA (*e.g.,* EPA+DHA+DPA; DHA+ALA) PUFA intake must be defined or described prospectively Studies must specify daily quantity of PUFA intake *Key Question 1:* For studies in children, ○ Include multicomponent interventions (*e.g.,* diet + exercise vs. exercise) ○ Infant formula	*Both Key Questions:* • Studies that do not quantify PUFA intake as either g/day or % of total energy intake from PUFA. • Analyses with PUFA intake as a continuous variable. • Fatty acid intake via infusion (not orally). • Food products or dietary supplements not widely available to U.S. consumers. • Multi-component interventions (*e.g.,* exercise + diet vs. exercise or plant sterols + diet vs. plant sterols) that do not isolate the effect or association of PUFA. • Multi-component interventions of statins + diet where statins are being initiated. Dietary interventions among existing statin users will be included. • Interventions designed to induce weight loss or treat overweight and obesity through energy restriction or hypocaloric diets. • Interventions designed for the purposes of treating medical conditions other than modifiable CV risk factors. • DHA and/or EPA n-3 FA dose >4 g/d. • Enteral feeding.
Comparators	*Both Key Questions:*	*Both Key Questions:*
	Dietary intake of a different level of fatty acids relevant to the exposure No added/supplement PUFA Placebo supplements	Diets with a caloric intake that are significantly higher or lower than the intervention/exposure diet. Diets or interventions that vary substantially in intake of macronutrients (or other factors) other than the intervention and comparator of interest. Different PUFA dietary exposure (*e.g.,* comparison of undefined quantiles).
Outcomes	*Key Question 1:* • Plasma lipoprotein concentrations ○ LDL cholesterol (LDL-c) ○ HDL cholesterol (HDL-c) ○ Non-HDL-cholesterol ○ Triglycerides (triacylglycerol) (Tg) ○ Lipoprotein(a) ○ Apolipoprotein B (ApoB)	*Key Question 1:* • Total cholesterol (TC). • TC:HDL ratio. • LDL:HDL ratio. • Chylomicrons. • VLDL-c. • IDL-c. • Other apolipoproteins. • Lipoprotein profiles. • Evaluations of fatty acid biomarker levels.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

[Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
	Key Question 2: • Cardiovascular events ○ Atherosclerotic cardiovascular disease (total) ○ Major adverse cardiac (or cerebral) events (MAC[C]E) ○ Specific cardiovascular events ▪ Myocardial infarction ▪ Coronary heart/artery disease ▪ Peripheral vascular/artery disease ○ Revascularization (for studies published after 1995) ○ Cardiovascular disease-related mortality ○ Stroke ○ Incident atrial fibrillation	*Key Question 2:* • Other cardiac or vascular related outcomes. • Participant reported events.
Subgroups/effect modifiers of interest.	*Both Key Questions:* • Specific life stages ○ Infants (for Key Question 1 only) ○ Children and adolescents (for Key Question 1 only) ○ Adults (19–64) ○ Older adults (≥65) ○ Pregnant or postpartum ○ Menopausal status • Other characteristics ○ Sex (male, female) ○ Socioeconomic status ○ Social determinants of health ○ Race/ethnicity ○ Physical activity level ○ Anthropometry ○ Health status, including type 2 diabetes ○ Percent of total energy intake replaced ○ Dietary trans fatty acid intake ○ Baseline lipid concentrations ○ Dietary cholesterol intake	None.
Design	*Key Question 1:* • Studies of adults ○ Parallel or cross-over randomized controlled trials (RCTs) ▪ n ≥25/group * • Studies of children ○ Parallel or cross-over RCTs ▪ n ≥25/group * ○ Nonrandomized comparative studies ▪ Must account for potential confounders ▪ n ≥50/group * *Key Question 2:* • Studies of adults ○ Parallel or cross-over RCTs ▪ n ≥25/group * ○ Nonrandomized comparative studies ▪ Must account for potential confounders ▪ Dietary intake must be defined or described prospectively ▪ We will aim for a minimum of about 10 observational studies for each specific PUFA—CV event pair (*e.g.,* EPA and stroke). We will thus select the largest observational studies within each category.† ▪ n ≥100/group	*Both Key Questions:* • Observational studies that do not account for confounders. • Analyses of dietary fat as a continuous variable (*e.g.,* RR per g/day intake) without an analysis at a threshold (*e.g.,* RR for > vs < threshold). • All other study designs.
Timing	*Key Question 1:* • Minimum intervention length: 4 weeks • In cross-over studies, any change in outcome measure must exclude data from the first week after end of any prior treatments	None.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

[Study eligibility criteria based on Population, Intervention, Comparator, Outcome (PICO), and other elements]

Element	Inclusion criteria	Exclusion criteria
	Key Question 2: • Minimum follow-up ○ If population has no CV risk factors (or unselected general population): 10 years ○ If population has one or more CV risk factors: 5 years	
Setting	• General community settings, including nursing homes, assisted living facilities, etc.	• Hospital or other acute care settings. • Institutionalized, confined settings (*e.g.,* prisons).
Publication	• English language • Published in peer-reviewed journals	

* Minimum sample size may be altered depending on the number of eligible studies found.

† Applying this approach for the 2016 AHRQ report n-3 fatty acids and cardiovascular disease (*https://doi.org/10.23970/AHRQEPCERTA223*), we included: for cardiac event outcomes, observational studies with at least 10,000 participants; for stroke outcomes, at least 3000 participants; for arrhythmia outcomes, at least 2000 participants; congestive heart failure outcomes, at least 700 participants; and for peripheral vascular disease events and MACE outcomes, at least 500 participants. In all instances, if a study meets eligibility criteria for any outcome, we will extract all outcomes of interest from that study; therefore, there will be multiple instances of studies being included for an outcome even though the study might not have met study size criteria for that specific outcome.

CV = cardiovascular; CVD = cardiovascular disease; PUFA = polyunsaturated fatty acids; ALA = alpha-linolenic acid; EPA = eicosapentaenoic aci; DHA= docosahexaenoic acid; DPA = docosapentaenoic acid; n-3 = Omega 3; n-6 = Omega 6; FA = fatty acid; c = cholesterol; LDL = low-density lipoprotein; IDL = intermediate-density lipoprotein; HDL high-density lipoprotein; TC—total cholesterol; Tg = Triglycerides/Triacylglycerols; apoA = apolipoprotein; MAC[C]E = Major adverse cardiac (or cerebro) events; BMI = body mass index; KQ = key question; N = number of participants.

Dated: November 21, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–27798 Filed 11–26–24; 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 5 U.S.C. 1009(d), 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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)—CE25–021, Research Grants for Preventing Violence and Violence Related Injury.

Dates: February 19–20, 2025.

Times: 10 a.m.–5 p.m., EST.

Place: Web Conference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Carlisha Gentles, Pharm.D., B.C.P.S., C.D.C.E.S., Scientific Review Officer, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, Georgia 30341. Telephone: (770) 488–1504; Email: *CGentles@cdc.gov.*

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

[FR Doc. 2024–27857 Filed 11–26–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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)—CE25–025, Rigorous Evaluation of Community- and Societal-Level Primary Prevention Approaches to Prevent Adverse Childhood Experiences (ACEs): Expanding the Best Available Evidence.

Dates: February 25–26, 2025.

Times: 10 a.m.–5 p.m., EST.

Place: Web Conference.

Agenda: To review and evaluate grant applications.