also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *First Commerce Bancorp, Inc., Lewisburg, Tennessee;* to acquire Peoples Bank of Middle Tennessee, Shelbyville, Tennessee.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2024–27573 Filed 11–22–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Dietary Saturated Fat Replacement 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 Saturated Fat Replacement 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 26, 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 Saturated Fat Replacement 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 Saturated Fat Replacement and Plasma Lipid and Cardiovascular Events.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/saturated-fat-replacement/protocol.*

This is to notify the public that the EPC Program would find the following information on *Dietary Saturated Fat Replacement 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 replacing dietary intake of total or individual saturated fatty acids with unsaturated, mono-unsaturated or polyunsaturated fatty acids, carbohydrates, or protein on plasma lipid concentrations in the general population?

KQ 2: What are the effects of replacing dietary intake of total or individual saturated fatty acids with unsaturated, mono-unsaturated or polyunsaturated fatty acids, carbohydrates, or protein 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 • Diets with a lower intake of total saturated fatty acids. • Diets with a lower intake of individual saturated fatty acids. • Diets with a lower intake of a combination of saturated fatty acids other than stearic acid (ranging from C8 to C16; *i.e.,* caprylic, caproic, lauric, myristic, palmitic). • Saturated fatty acid intake is exchanged for: ○ Carbohydrates, including different types (complex including fiber, refined, sugars). ○ Protein ○ Unsaturated fatty acids, any ○ Mono-unsaturated fatty acids (MUFA) ○ Polyunsaturated fatty acids (PUFA) ○ Combination of the above • Dietary intake must be defined or described prospectively (in real time). • Must specify daily quantity of dietary saturated fat 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 fatty acid intake as either g/day or % of total energy intake from saturated fat. • Analyses with fat intake as a continuous variable. • Fatty acid intake during a single meal or eating occasion. • Fatty acid intake via infusion (not orally). • Food products or dietary supplements not widely available to U.S. consumers. • Multi-component interventions (*e.g.,* diet + exercise vs. exercise or plant sterols + diet vs. plant sterols) (adult studies). • 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. • Enteral feeding.
Comparators	Both Key Questions • Diets with no exchange and, thus, a higher intake of total saturated fatty acids, individual saturated fatty acids, or combination of saturated fatty acids. • Well defined conventional or usual diet • Diets with same reduction in saturated fat intake but different replacement (*e.g.,* 6% saturated fatty acids in all arms, replaced with protein vs. replaced with carbohydrates).	Both Key Questions 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 dietary fat exposure (*e.g.,* comparison of undefined quantiles).
Outcomes	Key Question 1	Key Question 1

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
	• Plasma lipoprotein concentrations ..... ○ LDL cholesterol (LDL-c) ..... ○ HDL cholesterol (HDL-c) ..... ○ Non-HDL-cholesterol ..... ○ Triglycerides (triacylglycerol) (Tg) ..... ○ Lipoprotein(a) ..... ○ Apolipoprotein B (ApoB) ..... 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	• Total cholesterol (TC). • TC:HDL ratio. • LDL:HDL ratio. • Chylomicrons. • VLDL-c. • IDL-c. • Other apolipoproteins. • Lipoprotein profiles. • Evaluations of fatty acid biomarker levels. 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.	None.
	• 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.	
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. ▪ Dietary intake must be defined or described prospectively. ▪ n ≥50/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.

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 • 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 intervention—CV event pair (*e.g.,* reduced saturated fat and stroke). We will thus select the largest observational studies within each category.†. ▪ n ≥100/group.	
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 Key Question 2 • Minimum follow-up ○ If population has no CV risk factors: 10 years. ○ If population has one or more CV risk factors (or unselected general population): 5 years.	None.
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; MUFA = mono-unsaturated fatty acids; PUFA = polyunsaturated fatty acids; 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 19, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–27488 Filed 11–22–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–25–0047]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 16, 2024, to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated,