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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Dietary Total Fat Intake and Dietary Polyunsaturated Fatty Acid Intake and Child Growth and Development Outcomes: A Systematic Review

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 Total Fat Intake and Dietary Polyunsaturated Fatty Acid Intake and Child Growth and Development Outcomes: A Systematic Review,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 18, 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 Total Fat Intake and Dietary Polyunsaturated Fatty Acid Intake and Child Growth and Development Outcomes: A Systematic Review.* 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 Total Fat Intake and Dietary Polyunsaturated Fatty Acid Intake and Child Growth and Development Outcomes: A Systematic Review.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/child-growth-development-outcomes/protocol.*

This is to notify the public that the EPC Program would find the following information on *Dietary Total Fat Intake and Dietary Polyunsaturated Fatty Acid Intake and Child Growth and Development Outcomes: A Systematic Review* 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 is the association between dietary intake of omega-6 and/or omega-3 polyunsaturated fatty acids during pregnancy and risk of preterm birth?

KQ 1a: How are these associations affected by intervention/exposure characteristics (for example, the ratio of different fatty acids)?

KQ 2: What is the association between dietary intake of omega-6 and/or omega-3 polyunsaturated fatty acids during pregnancy and/or lactation and infant/child growth and developmental outcomes?

KQ 2a: How are these associations affected by intervention/exposure characteristics (for example, the ratio of different fatty acids)?

KQ 3: What is the association between dietary intake of total fat in individuals birth through 18 years of age and measures of growth and development?

KQ4: What is the association between dietary intake of omega-6 and/or omega-3 polyunsaturated fatty acids in individuals birth through 18 years of age and measures of growth and development?

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING/STUDY DESIGN)

Element	Inclusion criteria	Exclusion criteria
Population	*Exposure population:* • Individuals who are pregnant (KQ1) and/or lactating (KQ2) of any age or individuals from birth through 18 years of age (KQ3 and 4) from the general population (including those with overweight/obesity) not affected by a disease or health-related condition that impacts fat absorption and/or metabolism; or taking medications that alter the absorption or metabolism of dietary fatty acid *Outcome population:* • Offspring of the pregnant individual (birth through 18 years) not taking medications or affected by a disease or health-related condition that impacts fat absorption and/or metabolism *Note:* given the distinction between chronological age versus pubertal stage, as well as heterogeneity in enrollment across age ranges, for studies meeting all other eligibility criteria, we will consider exceptions to the age criterion.[a]	• Non-human participants (*e.g.,* animal studies, in-vitro models). • Studies that enroll participants taking medications or with diseases/health-related conditions that impact fatty acid absorption or metabolism (*e.g.,* Crohn's disease, ulcerative colitis, short-gut syndrome, cystic fibrosis, celiac). This includes cancer and malabsorption syndromes. • Studies that exclusively enroll participants hospitalized with an illness or injury. • Studies designed to induce weight loss or treat overweight and obesity through energy restriction or hypocaloric diets for the purposes of treating additional or other medical conditions. • Studies that exclusively enroll participants with severe undernourishment, underweight, stunting, or wasting. • Studies that enroll participants who are pre- or post-bariatric surgery. • Studies with enrollment *exclusively* of: pre-term babies (gestational age <37 weeks), babies admitted to the NICU, babies that have low birth weight (<2,500g) and/or babies that are small for gestational age (for assessment of infant and child growth parameters and developmental outcomes). • Studies that enroll infants with conditions treated/prevent by dietary supplementation (*e.g.,* G- or GJ-tubes, fatty acid oxidation disorders, necrotizing enterocolitis, attention deficit (and/or hyperactivity) disorder, ADHD, autism, etc.).
Intervention (Exposure)	*KQ1, 2, and 4:* • Dietary intake of total omega-3 PUFA, total omega-6 PUFA, or total PUFA (omega-3 and omega-6) • Dietary intake of individual PUFA (examples: linoleic, alpha-linolenic, EPA, DHA) • Dietary intake of a combination of long-chain PUFA (example: EPA+DHA+DPA; DHA+ARA) • Dietary intake of polyunsaturated fatty acids in terms of a ratio (example, n-6:n-3 PUFA, DHA:ARA) *KQ3:* • Total dietary fat intake (as either grams/day or % of total energy intake from fat) • A dietary pattern that describes and quantifies intake of total dietary carbohydrate, total fat, and total protein content (examples: low/high-fat diet; low/high-carbohydrate diet; high-protein; ketogenic diet) *Note:* Dietary intake can be from foods, supplements, and/or supplemented foods.[b]	*KQ1, 2, and 4:* • Studies that do not quantify PUFA intake as either grams/day or % of total energy intake from PUFA (*e.g.,* studies where exposure is number of fish servings per week). • Studies that do not provide absolute intake of fatty acids included in ratios. • Studies that only assess fatty acid biomarker wt% of total or concentrations. • Studies that only assess fatty acid intake via infusions (parenteral [intralipid] or stable isotope). • Studies that only assess exposure to fatty acids from a single meal, or eating occasion such that usual intake cannot be inferred. • Studies that examine food products or dietary supplements not widely available to U.S. consumers. • Multi-component interventions that do not isolate the effect or association of the PUFA exposure. • Observational studies that do not account for any confounders. • Studies designed to induce weight loss or treat participants who are determined to be overweight and obese through energy restriction or hypocaloric diets for the purposes of treating additional or other medical conditions. *KQ3:* • Studies that do not describe the energy and entire macronutrient distribution of the diet (*i.e.,* studies that do not report total carbohydrate, total fat, and total protein contents of experimental or baseline diets).

PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING/STUDY DESIGN)—Continued

Element	Inclusion criteria	Exclusion criteria
Comparator	*KQ1, 2, and 4:* • Placebo • Dietary intake of a different amount of fatty acids relevant to the exposure: ○ Total omega-3 ○ Total omega-6 ○ Individual PUFA ○ Combination of long-chain PUFA ○ Intake of PUFA in terms of a ratio *KQ3:* • Dietary intake of a different amount of total fat	• Diet(s) with an energy intake that is statistically significantly higher or lower than the intervention/exposure diet (*e.g.,* not isocaloric comparison). • Studies that do not have a statistically significant difference between groups in PUFA or total fat intake. • Studies comparing undefined exposures (*e.g.,* comparisons of undefined quartiles).
Outcome	*KQ2, 3, and 4:* Infant and child (birth through 18 years) growth parameters • Birth weight • Weight and Weight-for-age percentile or Z-score adjusted for gestational age • Length or Height and Length-for-age or Height-for-age percentile and Z-score adjusted for gestational age • Head circumference and Head circumference percentile and Z-score adjusted for gestational age Infant and child (birth through 18 years) developmental outcomes [c] • Cognitive/neurological • Language/communication • Movement/physical • Visual function/acuity • Social/emotional learning *KQ1:* • Risk of preterm birth	• BMI, BMI z-score. • Body composition and distribution (*e.g.,* % fat mass, fat-free mass, skin fold thicknesses). • Incidence and prevalence of overweight, obesity.
Timing	• All exposure or intervention durations will be included	
Setting	• Outpatient; all settings except hospital and acute care will be included	• Inpatient; hospital and acute care.
Study Design	• Randomized controlled trials • Prospective cohort studies • Nested case-control studies	• Narrative reviews. • Systematic reviews. • Meta-analyses. • Scoping reviews. • Umbrella reviews. • Retrospective cohort studies. • Non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies. • Cross-sectional studies. • Case-control studies. • All other study designs.
Geographic Location	• Locations with food products or dietary supplements widely available to U.S. and/or Canadian consumers • Countries rated very high on the Human Development Index (HDI) [d] at the time of data collection	• Locations not rated very high on the HDI.
Study Size	• Studies including power calculations or effect sizes • Studies with N ≥30 participants (for randomized clinical trials [RCTs]): ≥10 participants analyzed per study arm)	• Studies with N <30 participants (for RCTs: <10 participants analyzed per study arm), without power calculations or effect sizes. • Case studies and n = 1 samples. • Non-randomized studies that do not account for any potential confounders.
Language	• Articles published in English	• Articles published in languages other than English.
Publication Dates	• Articles published during or after 2000	• Articles published prior to 2000.

[a] For studies meeting all other eligibility criteria, studies enrolling populations aged 0 to older than 19 years will be included if: (a) results are stratified by age group, allowing extraction of data for participants aged through 18 years; or (b) 85% of the population is aged through 18 years, if results are not stratified by age group. The one exception is studies of adolescents; for those meeting all other eligibility criteria, studies enrolling adolescents through age 26, regardless of result stratification or percentage of population aged through 18 years, will be included. See the Study Selection section.

[b] Dietary supplement is defined as a product intended to supplement the diet that contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) intended to be taken by mouth as a pill, capsule, table, or liquid, and that is labeled on the front panel as being a dietary supplement.

[c] See Section IV for an example table of measures with periodicity.

[d] United Nations Development Programme Human Development Reports, *https://hdr.undp.org/data-center/human-development-index#/indicies/HDI*.

Dated: November 8, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–26783 Filed 11–15–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–25–25AW; Docket No. CDC–2024–0094]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Concussion Surveillance System. This data collection is designed to allow CDC to calculate the prevalence and incidence of traumatic brain injuries (TBI) for both adults and children, and the circumstances related to TBIs occurring in the preceding year.

DATES: CDC must receive written comments on or before January 17, 2025.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0094 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

National Concussion Surveillance System—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2014, an Institute of Medicine (IOM) report titled ''Sports-Related Concussions in Youth: Improving the Science, Changing the Culture,'' recommended that the U.S. Centers for Disease Control and Prevention (CDC) establish and oversee a national surveillance system to accurately determine the incidence of sports-related concussions [*i.e.,* mild traumatic brain injuries, or TBIs], including those in youth ages five to 21. The report further recommended that the cause, nature, and extent of the concussive injury also should be collected, including the sport or activity, level of competition, and signs and symptoms consistent with a concussion. The IOM recommendation was made because there were significant gaps in understanding of TBI, including concussion, incidence and prevalence estimates. Current non-fatal TBI surveillance estimates typically utilize emergency department (ED) or hospitalization-focused data sources. But these sources cannot account for injuries that go untreated or injuries diagnosed in primary care, urgent care, or specialty care settings, potentially missing information on millions of TBIs sustained each year. Without an accurate understanding of the burden, trends, and characteristics of these injuries, it is challenging to design or focus effective prevention programs, policies, or practices. The consequences from TBI are staggering, with many resulting in intensive and long-term care needs. This data collection could help fill significant knowledge gaps and inform prevention efforts across the country.

The purpose of this data collection is to calculate the 12-month prevalence and incidence of TBI for both adults and children, and the circumstances related to TBIs occurring in the preceding 12 months. The data collection instrument is largely based on the instrument used during the pilot that utilized cognitive testing prior to deployment. Data collected will include reports of head injuries experienced in the preceding 12 months, and the most recent head injury reported will be assessed for symptoms of TBI. We will also query respondents who sustained a head injury regarding the mechanism of injury (cause) and circumstances related to the TBI, medical care received, impact on social and school functioning, and information related to returning to work/school/play.

Data will be analyzed to produce nationally representative 12-month incidence and prevalence estimates of non-fatal TBI in children (ages 5–17) and adults. Data collected are likely to be used by state and local governments, researchers, voluntary health organizations, physicians, health educators, workplace wellness