160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on The Effect of Dietary Digestible Carbohydrate Intake on Risk of Cardiovascular Disease

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 *The Effect of Dietary Digestible Carbohydrate Intake on Risk of Cardiovascular Disease,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES:

E-mail 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 *The Effect of Dietary Digestible Carbohydrate Intake on Risk of Cardiovascular Disease.* 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 *The Effect of Dietary Digestible Carbohydrate Intake on Risk of Cardiovascular Disease.*

The entire research protocol is available online at:

https://effectivehealthcare.ahrq.gov/products/risk-cardiovascular-disease

This is to notify the public that the EPC Program would find the following information on

The Effect of Dietary Digestible Carbohydrate Intake on Risk of Cardiovascular Disease 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 e-mail list at: https://www.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 digestible carbohydrate intake and the incidence of cardiovascular disease?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

Inclusion and Exclusion Criteria by Population, Intervention, Comparator, Outcome, Timing, Setting/Study Design (PICOTS)

PICOTS Elements	Inclusion Criteria	Exclusion Criteria

Population	• Participants who are generally healthy, including participants who are determined to be overweight/obese, women who are pregnant or lactating
	• Age of participants
	  ○ Between 2 years and 9 years (before puberty)
	  ○ Between 9 and17 years
	  ○ 18 years and older
		• Participants with diseases/health-related conditions that impact carbohydrate absorption or metabolism, cancer, and malabsorption syndromes
		• Participants hospitalized with an illness or injury
		• Participants with the endpoint outcomes of CVD (i.e., studies that aim to treat participants already been diagnosed with the endpoint outcomes of interest)
		• Participants who intend to reduce weight or receive treatments for being overweight and having obesity through energy restriction or hypocaloric diets for the purposes of treating additional or other medical conditions
		• Participants who are determined to be undernourished, underweight, stunted, or wasted
		• Participants who are pre-bariatric or post-bariatric surgery
		• People younger than 2 years old

PICOTS Elements	Inclusion Criteria	Exclusion Criteria
Interventions	• Total dietary digestible carbohydrate intake from foods, beverages, and dietary supplements ○ Total dietary digestible carbohydrate intake defined as collective starch and sugar intake; carbohydrate intake not including dietary fiber • A dietary pattern that quantifies the intake of total dietary digestible carbohydrates and allows the isolation of the effect of carbohydrate intake from the effect of the intake of other macronutrients	• Studies that do not specify the amount of total digestible carbohydrate intake (e.g., studies that only report type or source of digestible carbohydrate) • Studies that do not describe the entire macronutrient distribution of the diet (i.e., studies that do not report total digestible carbohydrate, total fat, and total protein contents of experimental or baseline diets) • Studies that only assess digestible carbohydrate intake via infusions (rather than the GI tract) • Studies that primarily measure postprandial responses, as opposed to longer term studies • 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 digestible carbohydrate
Comparators	• Different total dietary digestible carbohydrate intake level(s)	• Comparison of different sources of carbohydrate without specifying amount of carbohydrate intake • Studies that do not attempt to control for energy intake of participants such that comparisons are made on an isocaloric basis. • Comparisons of available carbohydrate exposure should not be confounded by differences in participants' energy intake.

Outcomes	• Intermediate outcomes:
	  ○ LDL cholesterol (LDL)
	  ○ Total cholesterol (TC)
	  ○ HDL cholesterol (HDL)
	  ○ Non-HDL cholesterol
	  ○ TC:HDL ratio
	  ○ LDL:HDL ratio
	  ○ Triglycerides
	  ○ Blood pressure (systolic and/or diastolic) and hypertension
	• Final outcomes:
	  ○ Cardiovascular disease (e.g., myocardial infarction, coronary heart disease, congestive heart failure, peripheral artery disease)
	  ○ Stroke
	  ○ Cardiovascular disease-related mortality
		• Hypertensive disorders during pregnancy and/or lactation (e.g., chronic hypertension, gestational hypertension, preeclampsia-eclampsia, chronic hypertension with superimposed preeclampsia)

Timing	• At least 4 weeks	• Less than 4 weeks
Settings	• All except hospital and acute care	• Hospital and acute care

PICOTS Elements	Inclusion Criteria	Exclusion Criteria
Study design	• Randomized controlled trials • Nonrandomized controlled trials, including quasi-experimental and controlled before-and-after studies • Prospective cohort studies • Nested case-control studies • Relevant systematic reviews, or meta-analyses (used for identifying additional studies)	• In vitro studies, nonoriginal data (e.g., narrative reviews, scoping reviews, editorials, letters, or erratum), retrospective cohort studies, case series, qualitative studies, cost-benefit analysis, cross-sectional (i.e., nonlongitudinal) studies, survey
Publications	• Studies published in English only • Studies published in peer-reviewed journals • Studies published at and after the year 2000	• Non-English language studies

Abbreviations: CVD = cardiovascular disease; GI = gastrointestinal; HDL = high-density lipoprotein; KQ = Key Question; LDL = low-density lipoprotein PICOTS = populations, interventions, comparators, outcomes, timing, and settings; RCT = randomized controlled trial; TC = total cholesterol; U.S. = United States

Dated: January 8, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024-00505 Filed: 1/11/2024 8:45 am; Publication Date: 1/12/2024]