DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Fiber Intake and Laxation Outcomes

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 *Fiber Intake and Laxation Outcomes,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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

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5600 Fishers Lane

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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 *Fiber Intake and Laxation Outcomes.* 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 *Fiber Intake and Laxation Outcomes*. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/fiber-intake/protocol

This is to notify the public that the EPC Program would find the following information on *Fiber Intake and Laxation Outcomes* 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://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 Question (KQ)

KQ 1: What is the association between fiber intake and laxation/gut motility in apparently healthy individuals?

KQ 1a: How does the association vary among people in different life stages?

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	• Individuals of any age, including pregnant or lactating women
	• General population, including individuals with overweight/obese and those at elevated cardiometabolic disease risk
	  ○ Overweight/obese
	  ○ Hyperglycemia and related conditions, including type 2 diabetes
	  ○ Dyslipidemia
	  ○ Hypertension/high blood pressure
		• Those with diseases/health-related conditions or taking medications that could impact gut motility/laxation (e.g., irritable bowel syndrome; chronic constipation; lactose intolerance; use of medications that stimulate laxation or cause constipation)
		• Those with chronic constipation (100% of study population), including functional constipation
		• Study eligibility criteria includes "abnormal laxation" as defined by either a minimum or maximum number of defecations per week (or equivalent)
		• Those with other gastrointestinal-related conditions, symptoms, diagnoses
		  ○ Including diverticulosis
		• Those with diseases/health-related conditions or taking medications that could alter the gut microbiota composition/diversity (e.g., antibiotics)
		• Those with cancer, gastrointestinal disease, undernutrition, or who have had gut resection or bariatric surgery
		• Those with acute illness or injury
		• Pre-term babies (gestational age <37 weeks), babies with low birth weight (<2500 g) or small for gestational age (per study criteria)
		• Enteral/tube fed
		• Animal, *in vitro*, or other non-human studies

Element	Inclusion Criteria	Exclusion Criteria
Interventions	• Fiber intake, including different types and sources of fiber • Fiber naturally occurring in food, enriched in food, dietary supplements, and diets that can be defined on the basis of fiber content ○ Must specify quantity of fiber intake	• Diets (or other interventions or exposures) where the fiber intake has not been quantified or explicitly specified • Combinations of fiber (from food or dietary supplements) and other entities with a purported effect on motility, digestion, or microbiota (e.g., psyllium + probiotic) • Combinations of fiber supplements and other entities (e.g., minerals, vitamins)
Comparators	• Different levels (dosages) of fiber • No added fiber or placebo • Different types or sources of fiber • Different formulations of fiber	• Other entities with a purported effect on motility, digestion, or microbiota (e.g., probiotic) • Alternative food group diets (e.g., red meat, fish, high protein)
Interventions vs. Comparators	• Fiber (supplement) vs. no fiber (supplement) • Higher fiber (diet) vs. lower fiber (diet) • Fiber vs. alternative fiber • Fiber vs. alternative fiber dose • Fiber vs. alternative fiber formulation	• Fiber + probiotic (etc.) vs. no intervention or placebo • Fiber + probiotic (etc.) vs. same probiotic (etc.) • Fiber vs. probiotic (etc.) • High-fiber diet vs. red meat diet (etc.)

Outcomes	• Laxation (i.e., gut motility)
	  ○ Fecal frequency (e.g., number of defecations per week)
	  ○ Gastrointestinal transit time
	  ▪ Bristol stool scale (stool consistency)
	  ▪ Dye, marker studies
	  ○ Fecal output, weight/bulk (g/day)
	  ○ Ease of defecation (e.g., constipation)
		• Other disease or health outcomes
		• Flatulence, eructation, bloating, etc.

Subgroups of interest	• Specific life stages
	  ○ Infants
	  ○ Children and adolescents
	  ○ Adults (19-64)
	  ○ Older adults (≥65)
	  ○ Pregnant or postpartum
	  ○ Sex (male, female)
		None

Element	Inclusion Criteria	Exclusion Criteria
Design	• Randomized controlled trials ○ Parallel or cross-over • N ≥10/group	• Observational studies • All other study designs
Timing	• Minimum duration of intervention: 2 weeks • In cross-over studies, any change in outcome measure must exclude data from the first week after end of any prior treatments. This may be accomplished by a washout period of at least 1 week.	None
Setting	• General population	• Hospital or other acute care settings
Publication	• English language • Published in peer-reviewed journals	• Non-English language text • Conference abstracts and other non-peer-reviewed data

Dated: March 18, 2024.

Marquita Cullom,

Associate Director.

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