diabetes (in studies of CVD outcomes and risk factors)?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Populations

- Healthy adults (≥18 yr) without CVD or with low to intermediate risk for CVD
- Adults at high risk for CVD (*e.g.,* with diabetes, cardiometabolic syndrome, hypertension, dyslipidemia, non-dialysis chronic kidney disease)
- Adults with clinical CVD (*e.g.,* history of myocardial infarction, angina, transient ischemic attacks)
- Exclude populations chosen for having a non-CVD or non-diabetes-related disease (*e.g.,* cancer, gastrointestinal disease, rheumatic disease, dialysis)

Interventions/Exposures

- n-3 FA supplements
- n-3 FA supplemented foods (*e.g.,* eggs)
- n-3 FA content in diet (*e.g.,* from food frequency questionnaires)
- Biomarkers of n-3 FA intake
- n-3 content of food or supplements must be quantified (*e.g.,* exclude fish diet studies where only servings/week defined, Mediterranean diet studies without n-3 quantified). n-3 quantification can be of total n-3 FA, of a specific n-3 FA (*e.g.,* ALA) or of combined EPA+DHA (''marine oil'').
- Exclude n-3 FA dose ≥6 g/day (except for adverse events)
- Exclude weight loss interventions

Comparators

- Placebo or no n-3 FA intervention
- Different n-3 FA source intervention
- Different n-3 FA concentration intervention
- Different n-3 FA dietary exposure (*e.g.,* comparison of quantiles)
- Different n-3 FA biomarker levels (*e.g.,* comparison of quantiles)

Outcomes

- All-cause mortality
- Cardiovascular, cerebrovascular, and peripheral vascular events:
  - Fatal vascular events (*e.g.,* due to myocardial infarction, stroke)
  - Non-fatal vascular events (*e.g.,* myocardial infarction, stroke/cardiovascular accident, transient ischemic attack, unstable angina)
  - Coronary heart disease, new diagnosis
  - Congestive heart failure, new diagnosis
  - Cerebrovascular disease, new diagnosis
  - Peripheral vascular disease, new diagnosis
  - Ventricular arrhythmia, new diagnosis
  - Supraventricular arrhythmia, new diagnosis
  - Major vascular interventions/procedures (*e.g,* revascularization, thrombolysis, lower extremity amputation, defibrillator placement)
- Major CVD risk factors (intermediate outcomes):
  - Blood pressure (new-onset hypertension, systolic, diastolic, and mean arterial pressure)
  - Key plasma lipids (*i.e.,* high density lipoprotein cholesterol [HDL-c], low density lipoprotein cholesterol [LDL-c], total/HDL-c ratio, LDL-c/HDL-c ratio, triglycerides)
- Adverse events (*e.g.,* bleeding, major gastrointestinal disturbance), only from intervention studies of supplements

Timing

- Clinical outcomes, including new-onset hypertension (all study designs): ≥1 year followup (and intervention duration, as applicable)
- Intermediate outcomes (blood pressure and plasma lipids) (all study designs): ≥1 month followup
- Adverse events (all study designs): No minimum followup

Setting

Community-Dwelling (Non-Institutionalized) Individuals Study Design

- Randomized Controlled Trials (RCTs) (all outcomes)
- Randomized cross-over studies (blood pressure and plasma lipids, adverse events), minimum washout period to be determined
- Prospective nonrandomized comparative studies (clinical outcomes, adverse events)
- Prospective cohort (single group) studies, where groups are compared based on n-3 FA intake or intake biomarker values (clinical outcomes)
- Exclude: Retrospective or case control studies or cross-sectional studies (but include prospective nested case control studies). Studies must have measure of intake prior to outcome.
- Minimum sample sizes (All outcomes: To be determined)
- English language publications

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2015–19659 Filed 8–10–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Omega 3 Fatty Acids and Maternal and Child Health

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

ACTION: Request for Scientific Information Submissions.

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 of Omega 3 Fatty Acids and Maternal and Child Health, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Programs. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before September 10, 2015.

ADDRESSES: Online submissions: *http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/.* Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: *SIPS@epc-src.org.*

Print submissions:

Mailing Address:

Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503–220–8262 ext. 58653 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence for Omega 3 Fatty Acids and Maternal and Child Health.

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 Omega 3 Fatty Acids and Maternal and Child Health, including those that describe adverse events.

The entire research protocol, including the key questions, is also available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayProduct&productID=2083*.

This notice is to notify the public that the EPC Program would find the following information on Omega 3 Fatty Acids and Maternal and Child Health helpful:

- A list of completed studies that your organization has sponsored for this indication. 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, please provide a summary, including the following elements: 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 indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including 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 indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications 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 Web site 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: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/*.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayProduct&productID=2083*.

The Key Questions

KQ 1. Maternal Exposure

○ What is the efficacy of maternal interventions involving—or association of maternal exposures to—n-3 Fatty Acids (FA) (eicosapentaenoic acid [EPA], docosahexaenoic acid [DHA], EPA+DHA [long-chain n-3 FA], docosapentaenoic acid [DPA], alpha-linolenic acid [ALA], stearidonic acid [SDA] or total n-3 FA) on the following:

- Duration of gestation in women with or without a history of preterm birth (less than 37 weeks gestation)
- Incidence of preeclampsia/eclampsia/gestational hypertension in women with or without a history of preeclampsia/eclampsia/gestational hypertension
- Incidence of birth of small-for-gestational age human infants
- Incidence of ante- and/or postnatal depression in women with or without a history of major depression or postpartum depression

○ What are the associations of maternal biomarkers of n-3 intake during pregnancy and the outcomes identified above?

○ What are the effects of potential confounders or interacting factors (such as other nutrients or use of other supplements, or smoking status)?

○ How is the efficacy or association of n-3 FA on the outcomes of interest affected by the ratio of different n-3 FAs, as components of dietary supplements or biomarkers?

○ How does the ratio of n-6 FA to n-3 FA intakes or biomarker concentrations affect the efficacy or association of n-3 FA on the outcomes of interest?

○ Is there a threshold or dose-response relationship between n-3 FA exposures and the outcomes of interest or adverse events?

○ How does the duration of the intervention or exposure influence the effect of n-3 FA on the outcomes of interest?

KQ 2. Fetal/childhood exposures

○ What is the influence of maternal intakes of n-3 fatty acids or the n-3 fatty acid content of maternal breast milk (with or without knowledge of maternal intake of n-3 FA) or n-3 FA-supplemented infant formula or intakes of n-3 FA from sources other than maternal breast milk or supplemented infant formula on the following outcomes in term or preterm human infants?

- Growth patterns
- Neurological development
- Visual function
- Cognitive development
- Autism
- Learning disorders
- Attention Deficit Hyperactivity Disorder (ADHD)
- Atopic dermatitis
- Allergies
- Respiratory illness

○ What are the associations of the n-3 FA content or the n-6/n-3 FA ratio of maternal or fetal or child biomarkers with each of the outcomes identified above?

KQ 3. Maternal or childhood adverse events:

○ What are the short and long term risks related to maternal intake of n-3 FA during pregnancy or breastfeeding on:

- Pregnant women
- Breastfeeding women
- Term or preterm human infants at or after birth

○ What are the short and long term risks associated with intakes of n-3 FA by human infants (as maternal breast milk or infant formula supplemented with n-3 FA)?

○ Are adverse events associated with specific sources or doses?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Population(s)

• *KQ 1 (Maternal Exposures and Outcomes)*

○ Healthy pregnant women (for outcomes of birth weight, intrauterine growth restriction/small for gestational age, duration of gestation, risk of pre-eclampsia, eclampsia, or pregnancy hypertension)

○ Pregnant women with a history of pre-eclampsia, eclampsia, or pregnancy hypertension (only for outcome of risk of pre-eclampsia, eclampsia, or pregnancy hypertension)

○ Pregnant women with a history of major depressive disorder or postpartum depression (only for the outcome of risk for peripartum depression)

- *KQ 2 (In Utero and Postnatal (Through the First Year of Life) Exposures and Outcomes)*

○ Healthy preterm or full term infants of healthy women/mothers whose n-3 fatty acid exposures were monitored during pregnancy

○ Breastfed infants of healthy mothers whose n-3 fatty acid exposure was monitored and/or who participated in an n-3 fatty acid intervention during breastfeeding beginning at birth

○ Healthy preterm or full term infants with and without family history of respiratory conditions (for outcomes related to atopic dermatitis, allergy, respiratory conditions) of mothers whose n-3 exposures were monitored during pregnancy and/or breastfeeding

○ Healthy children or children with a family history of a respiratory disorder, a cognitive or visual development disorder, autism spectrum disorder, ADHD, or learning disabilities, age 0 to 18 years who participated in an n-3 fatty acid-supplemented infant formula intervention or an n-3 supplementation trial during infancy

- *KQ 3 (Adverse Events Associated With n-3 Interventions)*

○ Healthy pregnant women or pregnant women in the other categories described above

○ Offspring of women enrolled in an n-3 fatty acid intervention during pregnancy

○ Offspring of women whose exposure to n-3 fatty acids was assessed during pregnancy

○ Children whose exposure to n-3 fatty acids (through breast milk, infant formula, or supplementation) was monitored during the first year of life

Interventions/Exposures

- Interventions (KQ1, 2, 3 unless specified):

○ N-3 fatty acid supplements (*e.g.,* EPA, DHA, ALA, singly or in combination

○ N-3 fatty acid supplemented foods (*e.g.,* eggs) with quantified n-3 content

○ High-dose pharmaceutical grade n-3 fatty acids, *e.g.,* Omacor®, Ropufa®, MaxEPA®, Efamed, Res-Q®, Epagis, Almarin, Coromega, Lovaza®, Vascepa® (icosapent ethyl)

▪ Exclude doses of more than 6g/d, except for trials that report adverse events

○ N-3 fatty acid enriched infant formulae (KQ2,3)

▪ *E.g.,* Enfamil® Lipil®; Gerber® Good Start DHA & ARA®; Similac® Advance®

▪ N-3 enriched follow-up formulae

▪ Exclude parenterally administered sources

○ Marine oils, including fish oil, cod liver oil, and menhaden oil with quantified n-3 content

○ Algal or other marine sources of omega-3 fatty acids with quantified n-3 content

- Exposures (KQ1,2)

○ Dietary n-3 fatty acids from foods if concentrations are quantified in food frequency questionnaires

○ Breast milk n-3 fatty acids (KQ2)

○ Biomarkers (EPA, DHA, ALA, DPA, SDA), including but not limited to the following:

▪ Plasma fatty acids

▪ Erythrocyte fatty acids

▪ Adipocyte fatty acids

Comparators

- Inactive comparators:

○ Placebo (KQ1, 2, 3)

○ Non-fortified infant formula (KQ2)

- Active comparators

○ Different n-3 sources

○ Different n-3 concentrations (KQ1, 2, 3)

○ Alternative n-3 enriched infant formulae (KQ2)

○ Soy-based infant formula (KQ2)

○ Diet with different level of Vitamin E exposure

Outcomes

- Maternal outcomes (KQ1)

○ Blood pressure control

▪ Incidence of gestational hypertension

▪ Maternal blood pressure

▪ Incidence of pre-eclampsia, eclampsia

○ Peripartum depression

▪ Incidence of antepartum depression [10]

▪ Incidence of postpartum depression, *e.g.*

▪ Edinburgh Postnatal Depression scale

▪ Structured Clinical Interview (SCI)

○ Gestational length

▪ Duration of gestation

▪ Incidence of preterm birth

○ Birth weight

▪ Mean birth weight

▪ Incidence of low birth weight/small for gestational age

- Pediatric Outcomes (KQ2)

○ Neurological/visual/cognitive development

▪ Visual development, *e.g.*

▪ Visual evoked potential acuity

▪ Visual acuity testing

▪ Teller's Acuity Card test

▪ Electroretinography

▪ Cognitive/neurological development, *e.g.*

▪ EEGs as measure of maturity

▪ Psychomotor developmental index from Bayley's scales

▪ Bayley's mental development index

▪ Knobloch, Passamanick, and Sherrard's developmental Screening Inventory scores

▪ Neurological impairment assessment

▪ Active sleep, quiet sleep, sleep-wake transition, wakefulness

▪ Fagan Test of Infant Intelligence

▪ Stanford-Binet IQ

▪ Receptive Vocabulary

▪ Peabody Picture Vocabulary Test-Revised

▪ Auditory development

▪ Nerve conduction test

▪ Latency Auditory evoked potential

○ Risk for ADHD

▪ Studies will be included only if they employ a validated evaluation procedure

▪ E.g., Wechsler Intelligence Scale for Children

▪ Behavioral rating scales, *e.g.,* Connors, Vanderbilt, and Barkley scales

○ Risk for Autism spectrum disorders

▪ Studies will be included only if they employ a validated evaluation procedure

▪ *E.g.,* Modified Checklist of Autism in Toddlers

○ Risk for learning disabilities

▪ Studies will be included only if they employ a validated evaluation procedure

○ Risk for atopic dermatitis

○ Risk for allergies

▪ Studies will be included only if they employ a validated allergy assessment procedure, preferably challenge

○ Incidence of respiratory disorders

▪ Spirometry in children 5 and over (peak expiratory flow rate [PEFR] and forced expiratory volume in 1 second [FEV1])

- KQ 3: Adverse effects of intervention(s)

○ Incidence of specific adverse events reported in trials by study arm

Timing

- Duration of intervention or follow-up

○ Key Question 1,3 (maternal interventions/exposures):

▪ Interventions implemented anytime during pregnancy but preferably during the first or second trimester

▪ Followup duration is anytime during pregnancy (for maternal outcomes of pre/eclampsia or maternal hypertension); term (for outcomes related to birth weight, duration of pregnancy); or within the first 6 months postpartum (for the outcome of postpartum depression)

○ Key Question 2, 3 (infant exposures):

▪ Interventions implemented within one month of birth or exposures measured within 1 month of birth

- Followup duration is 0 to 18 years

Settings

- Community-dwelling individuals seen by primary care physicians or obstetricians in private or academic medical practices (KQ1, 3)
- Community dwelling children seen in outpatient health care or educational settings (KQ2, 3)

Study designs will be limited to Randomized Controlled Trials, prospective cohort studies, and nested case control studies (cross-sectional, retrospective cohort, and case study designs will be excluded; studies must have measure of intake/exposure prior to outcome). Language will be restricted to English. Only peer-reviewed studies will be included; unpublished studies will not be included.

Sharon B. Arnold,

Deputy Director.

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BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed changes to the currently approved information collection project: *''Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey Comparative Database.''* In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by October 13, 2015.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov*.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey Comparative Database

The CAHPS Clinician and Group Survey (''the CAHPS CG Survey'') is a tool for collecting standardized information on patients' experiences with physicians and staff in outpatient medical practices. The results, enable clinicians and administrators to assess and improve patients' experiences with medical care. The CAHPS CG Survey is a product of the CAHPS® program, which is funded and administered by AHRQ, and CAHPS® is a registered trademark of AHRQ. AHRQ works closely with a consortium of public and private research organizations to develop and maintain surveys and tools to advance patient-centered care. In 1999, the CAHPS Consortium began work on a survey that would assess patients' experiences with medical groups and clinicians. The CAHPS Consortium developed a preliminary instrument known as the CAHPS Group Practices Survey (G–CAHPS), with input from the Pacific Business Group on Health, which developed a Consumer Assessment Survey that is the precedent for this type of instrument.

In August 2004, AHRQ issued a notice in the **Federal Register** inviting organizations to test the CAHPS CG Survey. These field-test organizations were crucial partners in the evolution and development of the instrument, and provided critical data illuminating key aspects of survey design and administration. In July 2007 the CAHPS CG Survey was endorsed by the National Quality Forum (NQF), an organization established to standardize health care quality measurement and reporting. The endorsement represents the consensus of many health care providers, consumer groups, professional associations, purchasers, federal agencies, and research and quality organizations. The CAHPS CG Survey and related toolkit materials are available on the CAHPS Web site at *https://cahps.ahrq.gov/surveys-guidance/cg/instructions/index.html*. Since its release, the survey has been used by thousands of physicians and medical practices across the U.S.

The current CAHPS Consortium includes AHRQ, the Centers for Medicare & Medicaid Services (CMS), RAND, Yale School of Public Health, and Westat.

AHRQ developed the database for CAHPS CG Survey data following the CAHPS Health Plan Database as a model. The CAHPS Health Plan Database was developed in 1998 in response to requests from health plans, purchasers, and CMS for comparative data to support public reporting of health plan ratings, health plan accreditation and quality improvement (OMB Control Number 0935–0165, expiration 5/31/2017). Demand for comparative results from the CG Survey has grown as well, and therefore AHRQ developed a dedicated CAHPS Clinician and Group Database to support benchmarking, quality improvement, and research (OMB Control Number 0935–0197, expiration 06/30/2015).

The CAHPS Database contains data from AHRQ's standardized CAHPS Surveys which provide comparative measures of quality to health care purchasers, consumers, regulators, and policy makers. The CAHPS Database also provides data for AHRQ's annual National Healthcare Quality and Disparities Report.

Health systems, medical groups and practices that administer the CAHPS Clinician & Group Survey according to CAHPS specifications can participate in this project. A health system is a complex of facilities, organizations, and providers of health care in a specified geographic area. A medical group is defined as a medical group, Accountable Care Organization (ACO), state organization or some other grouping of medical practices. A practice is an outpatient facility in a specific location whose physicians and other providers share administrative and clinical support staff. Each practice located in a building containing multiple medical offices is considered a separate practice.

The goal of this project is to renew the CAHPS CG Database. This database will continue to update the CAHPS CG Database with the latest results of the CAHPS CG Survey. These results consist of 34 items that measure 5 areas or composites of patients' experiences with physicians and staff in outpatient medical practices. This database:

(1) Allows participating organizations to compare their survey results with those of other outpatient medical groups;

(2) Provides data to medical groups and practices to facilitate internal assessment and learning in the quality improvement process; and

(3) Provides information to help identify strengths and areas with potential for improvement in patient care. The five composite measures are:

Getting Timely Appointments, Care, and Information

How Well Providers Communicate With Patients