

information pursuant to section 54.804(a) of the Commission's rules, replacing section 54.315(a) of the Commission's rules. 47 CFR 54.315(a), 54.804(a). The Commission also intends to make several revisions to FCC Form 183, including text changes to reflect the Rural Digital Opportunity Fund auction. Based on the Commission's experience with auctions and consistent with the record, this two-stage collection of information balances the need to collect information essential to conduct a successful auction with administrative efficiency.

Under this information collection, the Commission will collect information that will be used to determine whether an applicant is legally qualified to participate in an auction for Rural Digital Opportunity Fund support. To aid in collecting this information, the Commission will use FCC Form 183, which the public will use to provide the necessary information and certifications. Commission staff will review the information collected on FCC Form 183 as part of the pre-auction process, prior to the start of the auction, and determine whether each applicant satisfies the Commission's requirements to participate in an auction for Rural Digital Opportunity Fund support. Without the information collected on FCC Form 183, the Commission will not be able to determine if an applicant is legally qualified to participate in the auction and has complied with the various applicable regulatory and statutory auction requirements for such participation. This approach is an appropriate assessment of providers for ensuring serious participation without being unduly burdensome.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

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BILLING CODE 6712-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Safety of Vaccines Used for Routine Immunization in the United States

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

ACTION: Request for Supplemental Evidence and Data 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 on *Safety of Vaccines Used for Routine Immunization in the United States*, 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 30 days after the date of this publication in the **Federal Register**.

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:

Jenae Bennis, Telephone: 301-427-1496 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 *Safety of Vaccines Used for Routine Immunization in the United States*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

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 *Safety of Vaccines Used for Routine Immunization in the United States*, including those that describe adverse events. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/safety-vaccines/protocol>.

This is to notify the public that the EPC Program would find the following information on *Safety of Vaccines Used for Routine Immunization in the United States* 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*, 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 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 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 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://www.effectivehealthcare.ahrq.gov/email-updates>.

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.

Key Questions (KQ)

KQ 1: What is the evidence that vaccines included in the immunization schedule recommended for adults in the United States (<https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>) are safe in the short term (within 42 days following immunization) or long term (>42 days after immunization)?

KQ1a. What adverse events (AEs) are collected in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

KQ1b. What AEs are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

KQ1c. What AEs are associated with these vaccines?

1. For each AE associated with a particular vaccine, what is the average severity and frequency?

2. For AEs without statistically significant associations with a particular vaccine, what is the range of possible effects?

3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

KQ 2: What is the evidence that vaccines included in the immunization schedules recommended for children and adolescents in the United States (<https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>) are safe in the short term (within 42 days following immunization) or long term (>42 days after immunization)?

KQ2a. What AEs are collected in clinical studies (Phases I–IV) and in

observational studies containing a control/comparison group?

KQ2b. What AEs are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

KQ2c. What AEs are associated with these vaccines?

1. For each AE associated with a particular vaccine, what is the average severity and frequency?

2. For AEs without statistically significant associations with a particular vaccine, what is the range of possible effects?

3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether a vaccine is administered individually or in a combination vaccine product, schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

KQ 3: What is the evidence that vaccines recommended for pregnant women in the United States are safe in the short term (within 42 days following immunization) or long term (>42 days after immunization) for both the woman and her fetus/infant?

KQ3a. What AEs are collected in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

KQ3b. What AEs are reported in clinical studies (Phases I–IV) and in observational studies containing a control/comparison group?

KQ3c. What AEs are associated with these vaccines?

1. For each AE associated with a particular vaccine, what is the average severity and frequency?

2. For AEs without statistically significant associations with a particular vaccine, what is the range of possible effects?

3. For each AE associated with a particular vaccine, what are the risk factors for the AE (including age, sex, race/ethnicity, genotype, underlying medical condition, whether the vaccine is administered individually or in a combination vaccine product, the schedule of vaccine administration, adjuvants, and medications administered concomitantly)?

KQ3d. What AEs are associated with these vaccines in the fetus/infant?

1. For each AE associated with a particular vaccine, what is the average severity and frequency?

2. For AEs without statistically significant associations with a particular vaccine, what is the level of certainty?

3. For each AE associated with a particular vaccine, what are risk factors for the AE (including age, gender, race/ethnicity, genotype, underlying medical condition, whether vaccine administered individually or in a combination vaccine product, vaccine schedule of administration, adjuvants, medications administered concomitantly)?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)

| Domain | Inclusion | Exclusion |
|---------------------|---|---|
| Population | <ul style="list-style-type: none"> Human participants of all ages for whom the vaccines are recommended in the United States. | <ul style="list-style-type: none"> Studies in animals or mechanistic/in vitro studies. Studies exclusively in populations for whom the vaccine is not approved or is contraindicated. |
| Interventions | <p>All KQs</p> <ul style="list-style-type: none"> Individual vaccines included in the immunization schedule recommended for adults, children and adolescents, and pregnant women, as well as combination vaccines available in the United States.. <p>Vaccines for adults (KQ1).</p> | <ul style="list-style-type: none"> Studies of vaccines not on the United States recommended schedules, including brands/formulations not available in the United States, or no longer used. |

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

| Domain | Inclusion | Exclusion |
|----------------------|--|---|
| | <ul style="list-style-type: none"> Hepatitis A (HepA; Havrix, Vaqta); hepatitis B (HepB; Engerix-B, Recombivax HB, HEPLISAV-B); HepA-Hep B (Twinrix); Haemophilus influenzae type b (Hib; PedvaxHIB, ActHIB, Hiberix); human papillomavirus (HPV, HPV9; Gardasil 9); inactivated influenza (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone High Dose, Fluzone Quadrivalent, Fludax); live attenuated influenza (LAIV; FluMist Quadrivalent); recombinant influenza (RIV; Flublok Quadrivalent); measles, mumps, rubella (MMR; M-M-R II); meningococcal (Menactra [MenACWY-D], Menveo [MenACWY-CRM]); Meningococcal B (MenB; Bexsero [MenB-4C], Trumenba [MenB-FHbp]); pneumococcal conjugate vaccine (PCV13; Prevnar 13); pneumococcal polysaccharide vaccine (PPSV23; Pneumovax); tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix); tetanus, diphtheria (Td; TDVAX, Tenivac); varicella (VAR; Varivax); zoster (recombinant, RZV; live, ZVL; Shingrix, Zostavax). <p>Children and Adolescents (KQ 2).</p> <ul style="list-style-type: none"> Vaccines for children and adolescents will include diphtheria, tetanus, & acellular pertussis (DTaP; Daptacel, Infanrix); hepatitis A (HepA; Havrix, Vaqta); hepatitis B (HepB; Engerix-B, Recombivax HB); Haemophilus influenzae type b (Hib; PedvaxHIB, ActHIB, Hiberix); human papillomavirus (HPV, HPV9; Gardasil 9); inactivated polio vaccine (IPV; IPOL); inactivated influenza (IIV; Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent); live attenuated influenza (LAIV; FluMist Quadrivalent); measles, mumps, rubella (MMR; M-M-R II); meningococcal (MenACWY-D, Men-ACWY-CRM; Menactra [MenACWY-D], Menveo [MenACWY-CRM]); meningococcal B (MenB; Bexsero [MenB-4C], Trumenba [MenB-FHbp]); pneumococcal conjugate vaccine (PCV13; Prevnar 13); pneumococcal polysaccharide vaccine (PPSV23; Pneumovax); rotavirus (RV; Rotarix, RotaTeq); tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix); varicella (VAR; Varivax); DTaP-HepB-IPV (Pediarix); DTaP-IPV/Hib (Pentacel); DTaP-IPV (Kinrix, Quadracel); MMR-V (ProQuad); DTaP-IPV-Hib-HepB (Vaxelis). <p>Vaccines for pregnant women (KQ3).</p> <ul style="list-style-type: none"> Hepatitis B (HepB; Engerix-B, Recombivax HB, HEPLISAV-B); inactivated influenza (IIV; Afluria Quadrivalent, Flucelvax Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, Fluzone Quadrivalent); recombinant influenza (RIV; Flublok Quadrivalent); tetanus, diphtheria, & acellular pertussis (Tdap; Adacel, Boostrix). | |
| Comparators | <ul style="list-style-type: none"> Active comparators (e.g., other vaccines or other vaccination schedules) and inactive comparators (e.g., no vaccine). | <ul style="list-style-type: none"> Studies without intervention comparator. |
| Outcomes | <ul style="list-style-type: none"> Adverse events identified in participants, and, in the case of pregnant women, in their fetuses/infants (including the presence and the absence of harms, toxicities, transient side effects, and unintended adverse health effects). | <ul style="list-style-type: none"> Studies reporting only on effectiveness outcomes. |
| Timing | <ul style="list-style-type: none"> Short term (within 30–42 days following immunization) as well as long term (>42 days after immunization) effects. | <ul style="list-style-type: none"> No exclusions apply. |
| Setting(s) | <ul style="list-style-type: none"> No restrictions with regard to settings. | |
| Study design | <ul style="list-style-type: none"> Controlled studies (randomized and non-randomized controlled clinical trials, cohort studies comparing two or more cohorts, case-control studies, self-controlled case series). | <ul style="list-style-type: none"> Studies without comparator (e.g., case studies*). |
| Other limiters | <ul style="list-style-type: none"> English language scientific journal publications and trial records with published results. | <ul style="list-style-type: none"> Studies published in abbreviated form only (e.g., letters, conference abstracts). Studies reported only in non-English publications. |

* Case studies are outside the scope of the review because they do not include unvaccinated individuals for comparison.

Dated: April 15, 2020.

Virginia Mackay-Smith,

*Associate Director, Office of the Director,
AHRQ.*

[FR Doc. 2020-08331 Filed 4-17-20; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS)

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS). This meeting is open to the public limited only by the audio (via teleconference) lines available. The public is welcome to listen to the meeting, please use the following URL https://www.cdc.gov/nchs/about/bsc/bsc_meetings.htm that points to the BSC homepage. Further information and meeting agenda will be available on the BSC website including instructions for accessing the live meeting broadcast.

DATES: The meeting will be held on May 5, 2020, 11:00 a.m.–1:30 p.m., EDT.

ADDRESSES: The teleconference access is https://www.cdc.gov/nchs/about/bsc/bsc_meetings.htm.

FOR FURTHER INFORMATION CONTACT:

Sayedha Uddin, M.D., M.P.H., Executive Secretary, NCHS/CDC, Board of Scientific Counselors, 3311 Toledo Road, Room 2627, Hyattsville, Maryland 20782, telephone (301) 458-4303, isx9@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters to be Considered: The agenda will include discussion on items per the scope of the Charter. The meeting agenda includes welcome remarks and a Center update by NCHS leadership; update on Patient Centered Outcomes Research Trust Fund Projects. Agenda

items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

*Director, Strategic Business Initiatives Unit,
Office of the Chief Operating Officer, Centers
for Disease Control and Prevention.*

[FR Doc. 2020-08213 Filed 4-17-20; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP) GH20-001, Develop, Implement, and Evaluate Evidence-Based, Innovative Approaches To Prevent, Find, and Cure Tuberculosis in High-Burden Settings; GH20-002, Malaria Operations Research To Improve Malaria Control and Reduce Morbidity and Mortality in Western Kenya; GH20-003, Conducting Public Health Research in Colombia; GH20-004, Conducting Public Health Research in Georgia; and GH20-005, Conducting Public Health Research in South America; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—GH20-001, Develop, Implement, and Evaluate Evidence-based, Innovative Approaches to Prevent, Find, and Cure Tuberculosis in High-Burden Settings; GH20-002, Malaria Operations Research to Improve Malaria Control and Reduce Morbidity and Mortality in Western Kenya; GH20-003, Conducting Public Health Research in Colombia; GH20-004, Conducting Public Health Research in Georgia; and GH20-005, Conducting Public Health Research in South America; April 14–16, 2020, 9:00 a.m.– 2:00 p.m., EDT, in the amended FRN.

The teleconference, which was published in the **Federal Register** on April 1, 2020, Vol. 85, No. 63, page 18243, is being amended to change the meeting dates and times to: April 14–15,

2020, from 9:00 a.m.–2:00 p.m., EDT. The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT:

Hylan Shoob, Ph.D., Scientific Review Officer, Center for Global Health, CDC, 1600 Clifton Road NE, Atlanta, Georgia 30329-4027, Telephone (404) 639-4796; HShoob@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

*Director, Strategic Business Initiatives Unit,
Office of the Chief Operating Officer, Centers
for Disease Control and Prevention.*

[FR Doc. 2020-08214 Filed 4-17-20; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-P-0015A]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to